



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 2, 702, 703, 704, 707, 716, 717, 720, 723, 725, and 790

[EPA-HQ-OPPT-2021-0419; FRL-8223-01-OCSPP]

RIN 2070-AK68

Confidential Business Information Claims under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing new and amended requirements concerning the assertion and treatment of confidential business information (CBI) claims for information reported to or otherwise obtained by EPA under the Toxic Substances Control Act (TSCA). Amendments to TSCA in 2016 included many new provisions concerning the assertion, Agency review, and treatment of confidentiality claims. This document proposes procedures for submitting such claims in TSCA submissions. It addresses issues such as substantiation requirements, exemptions, electronic reporting enhancements (including expanding electronic reporting requirements), maintenance or withdrawal of confidentiality claims, and provisions in current rules that are inconsistent with amended TSCA. The proposed rule also addresses EPA procedures for reviewing and communicating with TSCA submitters about confidentiality claims.

DATES: Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2021-0419, using the Federal eRulemaking Portal at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the

docket, along with more information about dockets generally, is available at

<https://www.epa.gov/dockets>.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and reading room is open by appointment only. For the latest status information on EPA/DC services and in-person docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Jessica Barkas, Project Management and Operations Division (7401), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 250-8880; email address: barkas.jessica@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you have submitted or expect to submit information to EPA under TSCA and have made or expect to make any confidentiality claims concerning that information. Persons who seek information on such submissions may also be affected by this action. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers, importers, or processors of chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

If you have any questions regarding the applicability of this action to a particular entity, consult the technical contact person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

TSCA section 14, 15 U.S.C 2613, includes requirements for asserting confidentiality claims and for EPA review of such claims to determine whether the information is entitled to the requested protections. Implementing rules are explicitly contemplated for some provisions of TSCA section 14 (e.g., TSCA section 14(c)(1)(a) requires persons seeking to protect information from disclosure to assert such a claim concurrent with submission of the information, in accordance with existing or future rules; TSCA section 14(c)(3) generally requires that confidentiality claims be substantiated “in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section”). In addition, other TSCA section 14 requirements imply authority to promulgate rules addressing the form and manner in which those requirements should be fulfilled (e.g., manner of submitting confidentiality claims, manner in which EPA will make required notices under TSCA sections 14(g) or 14(e)).

Discussion of authority to require electronic reporting under TSCA may be found in the preamble to the final rule entitled “Electronic Reporting under the Toxic Substances Control Act; Final Rule” (Ref. 1). In addition, the Government Paperwork Elimination Act (GPEA), 44 U.S.C. 3504, provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public.

C. What action is the Agency taking?

EPA is proposing new and amended requirements concerning the assertion and treatment of CBI claims under TSCA, 15 U.S.C. 2601, *et seq.* The Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016, Pub. L. 114–182 (referred to in this Notice as “the Lautenberg amendments”), made significant amendments to TSCA, including new provisions governing the assertion and review of CBI claims that EPA is proposing to implement in this action.

In this document, EPA is proposing to specify procedures for submitting and supporting CBI claims under TSCA, including among other things: (1) Substantiation requirements applicable at the time of submission; (2) Electronic reporting requirements; (3) Requirements to

provide certification statements and generic names when making confidentiality claims; (4) Treatment of information used for TSCA purposes that EPA could obtain under TSCA but was originally submitted via other means; and (5) Maintenance or withdrawal of confidentiality claims.

EPA is also proposing to specify procedures for reviewing and communicating with TSCA submitters about confidentiality claims, including requirements for submitters to maintain contact information, and procedures for EPA to provide notices to submitters concerning their claims.

EPA is proposing new provisions, as well as to amend and reorganize existing provisions concerning assertion of confidentiality claims under TSCA. Regulatory provisions concerning TSCA CBI claims are currently spread over a large number of parts in the Code of Federal Regulations (CFR). EPA has general provisions regarding confidentiality claims at 40 CFR part 2, subpart B. Those general provisions are accompanied by sections pertaining to confidentiality for many of the statutes administered by the Agency. The TSCA-specific provisions of the Agency's general business confidentiality regulations are at 40 CFR 2.306. In addition, many of the specific TSCA regulations in title 40 of the CFR contain their own provisions regarding CBI, such as in parts 711 (Chemical Data Reporting) and 720 (Premanufacture Notification).

In this proposed rule, most procedural requirements for asserting and maintaining confidentiality claims would be organized into a proposed new part of title 40 of the CFR, i.e., in part 703. The provisions in proposed part 703 would apply to any TSCA submission, except as modified elsewhere in part 2 or other TSCA-specific regulations, as spelled out in this proposed rule. Further discussion of the interactions between the various provisions regarding confidentiality can be found in Unit II.B. of this document.

D. What are the incremental costs and benefits of this action?

EPA has evaluated the potential incremental impacts of this proposed rulemaking, including alternative options. The details are presented in the economic analysis prepared for the

proposed rule (Ref. 2), which is available in the docket and is briefly summarized here.

The benefits of the proposed rule include improvements to EPA's management of CBI, specifically in cases of deficient claims, and improved communication and increased public transparency for chemical information. The proposed rule is expected to decrease the frequency of submitter error and increase efficiency in the processes for asserting and maintaining CBI claims. Lastly, the proposed rule would bring TSCA confidentiality regulations in line with the changes to TSCA section 14 brought about by the Lautenberg amendments.

EPA estimates that the public will incur a one-time burden and cost of approximately 2,945 hours with an associated cost of approximately \$271,000 in the first year after the rule is finalized and an annual, ongoing burden of approximately 525 hours with an associated cost of approximately \$45,000 in each following year.

E. Are there potentially disproportionate impacts for children health?

The proposed rule does not involve environmental health or safety risks that the EPA has reason to believe may disproportionately affect children. However, the Agency believes that the information collected under this proposed rule, if finalized, will assist EPA and others in evaluating potential hazards and risks associated with chemicals. Although not directly impacting environmental health or safety risks, this information will enable the Agency to better protect human health and the environment, including the health of children.

F. What are the environmental justice impacts?

This proposed action does not address human health or environmental risks or otherwise have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples. Although not directly impacting environmental justice-related concerns, the information collected under this proposed rule will enable the Agency to better protect human health and the environment, including in low-income and minority communities.

II. Background

The Lautenberg amendments included several significant changes to TSCA section 14. These include requirements that persons submitting information under TSCA substantiate most confidentiality claims at the time of submission, as well as additional statement, certification, and generic name requirements. Under TSCA section 14(e), in order to maintain most claims beyond a 10-year period, submitters are required to reassert and resubstantiate those claims. Several new requirements also apply to EPA, including requirements at TSCA section 14(g) to review and approve or deny all chemical identity claims asserted since the Lautenberg amendments were enacted concerning substances that are offered for commercial distribution, as well as a subset of all other confidentiality claims, within 90 days of assertion of the claim. Further requirements that EPA review all confidentiality claims for the chemical identity of substances listed as active on the TSCA Inventory, a requirement to assign and apply unique identifiers (UIDs) to substances with approved confidentiality claims for chemical identity, as well as new provisions providing expanded access to TSCA CBI, have been discussed in previous documents that published in the *Federal Register*, see e.g., Refs. 3 (about the CBI review plan), 4 (about UIDs) and 5 (about expanded access to CBI). Additionally, some TSCA regulations promulgated or amended since the Lautenberg amendments have included confidentiality provisions conforming to the amendments (e.g., Chemical Data Reporting at 40 CFR 711.30 and Active/Inactive Inventory Reporting at 40 CFR 710.37).

A. Existing Regulations Governing Confidentiality under TSCA

As proposed, this rulemaking would implement additional requirements of the Lautenberg amendments concerning confidentiality claims and would apply to all TSCA submissions. The proposal is intended to clarify the TSCA section 14 requirements for submitters of TSCA confidentiality claims. This would reduce the likelihood of claims being denied because of procedural insufficiencies and facilitate the public availability of information for which confidentiality is either not requested or not allowed under TSCA. The proposed procedural rules would aid efficient and timely EPA review of confidentiality claims and reduce

the likelihood of inadvertent disclosure of CBI.

Currently, CBI claims are asserted according to TSCA section 14 and existing TSCA rule requirements that are specific to certain reporting requirements (see Unit II.E. of this document). In some cases, further claim assertion procedures are included in EPA's general CBI regulations at 40 CFR part 2.

The procedures currently used by EPA to review TSCA CBI claims are found in 40 CFR part 2, subpart B. These regulations were developed to, among other things, apply Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. 552, relating to business confidentiality, to review CBI claims in response to a FOIA request. Some TSCA-specific provisions in 40 CFR 2.306 add to or modify the general CBI regulations found in 40 CFR 2.201 through 2.215. 40 CFR 2.306 was last modified in 1993. In the absence of revisions to accommodate the changes introduced by the Lautenberg amendments, EPA has continued to use the 40 CFR part 2 regulations to complete the mandatory confidentiality determinations required by the Lautenberg amendments.

The proposed rule would tailor all TSCA CBI claim assertion and review procedures to the requirements of TSCA rules and consolidate them in the TSCA rules - primarily in the proposed new part 703. 40 CFR 2.306 would be reduced in scope. It would clarify that most of the general claim assertion and review rules found in the 40 CFR part 2 CBI rules no longer apply to TSCA CBI claims and to elaborate on special circumstances where CBI may be disclosed based on the provisions of TSCA section 14(d) (disclosure to states, local governments and tribes under TSCA section 14(d)(4); health or environmental professionals under TSCA section 14(d)(5); or to certain emergency responders under TSCA section 14(d)(6) or as relevant to a proceeding under TSCA section 14(d)(7)). EPA is proposing to retain certain notice requirements in 40 CFR part 2 that are not required by TSCA Section 14. Specifically, under TSCA section 14(g)(2)(C)(iii), EPA is not required to provide notice prior to disclosure of information pursuant to TSCA sections 14(d)(1), (2), (7), or (8), i.e., to Federal employees or

officers, to contractors, if relevant to a proceeding, or required to be made public under other Federal law. EPA is proposing to retain certain existing notice requirements in 40 CFR part 2 for disclosure to Federal employees at 40 CFR 2.306(d), if relevant to a proceeding at 40 CFR 2.306(e), and for contractors and subcontractors at 40 CFR 2.306(f).

Additionally, the consolidation of TSCA CBI claim review procedures into the proposed new part 703 includes the review procedures relating to FOIA requests (i.e., CBI claim review required by TSCA section 14(f)(2)(A)). CBI claim review procedures in 40 CFR 2.306(d), (e), and (g), and the procedures in 40 CFR 2.204 and 2.205 that are currently cross-referenced in 40 CFR 2.306 are replaced with corresponding provisions in the proposed new part 703.

B. Purpose and Applicability

EPA intends for the proposed requirements to apply broadly to any information that is reported to, or otherwise obtained by, the Agency under TSCA. 15 U.S.C. section 2613(a)(1). This includes, for example, information that is submitted pursuant to a requirement of TSCA or its implementing regulations (e.g., a TSCA section 5 Premanufacture Notification (PMN) or a TSCA section 8(e) notice of substantial risk), information that is collected in the course of a TSCA inspection or other TSCA enforcement-related activity, and materials that are subpoenaed pursuant to TSCA. The proposed rule would also cover information which is first obtained by EPA under an authority other than TSCA but which meets the following criteria: (1) EPA has authority to collect the information under TSCA; and (2) the information is either used to satisfy the obligation of a person under TSCA or used by EPA in the course of carrying out its responsibilities under TSCA. EPA is proposing to interpret the phrase “that is reported to, or otherwise obtained by, the Administrator under TSCA” to include information that meets the two criteria identified above. The term “under” is not defined in TSCA section 14; therefore, EPA is proposing to interpret this term as it is commonly used as well as from its statutory context. *See Kucana v. Holder*, 558 U.S. 233, 245 (2010) (quoting *Ardestani v. INS*, 502 U.S. 129, 135 (1991)) (“The word ‘under’ ‘has many dictionary definitions and must draw its meaning from its

context.”). Dictionary definitions can provide some insight into how a reasonable or ordinary person would interpret the term. “Under” is defined as “subject to the authority, control, guidance, or instruction of,” *under*, Merriam-Webster Online (2021), and “subject to” is defined as “affected by or possibly affected by (something).” *Subject to*, Merriam-Webster Online (2021). In addition, the broad inclusive language used - “reported to, or otherwise obtained by” - suggests that Congress intended the provision to apply broadly. It applies not only to information reported under TSCA but also to information obtained under TSCA in manners other than reporting.

Language added to TSCA by the Lautenberg amendments also supports the proposed interpretation that any information EPA has the authority to collect under TSCA and is used for TSCA purposes should be considered obtained “under” TSCA. First, TSCA section 4(h)(3)(A) refers to the submission “under this subchapter” of voluntary information, suggesting information need not be required by a rule or order to be submitted “under” TSCA. Section 26(j) further provides that subject to TSCA section 14, the Administrator shall make available to the public “a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those studies.” 15 USC 2625(j)(4). Moreover, TSCA section 26(k) requires the Administrator to consider “reasonably available” information when conducting a risk evaluation. This language appears to suggest that TSCA section 14 would govern confidentiality determinations for *all* studies considered by the Agency under TSCA section 6(b), regardless of where the studies originated or how they were obtained.

However, there may be instances where information covered under proposed new part 703 was originally submitted to EPA pursuant to a statute with provisions regarding confidentiality, disclosure and treatment of information that materially differ from those in TSCA. EPA has addressed conflicts between regulatory provisions in 40 CFR 2.202(d), which states that the “rule which provides greater or wider availability to the public of the information shall govern,” and more specifically in the existing 40 CFR 2.306(b), which provides that under

the appropriate circumstances TSCA provisions would apply to certain information originally submitted to EPA for some non-TSCA purpose. But under the Lautenberg amendments to TSCA, EPA will be making use of significant amounts of data originating from a variety of sources, including existing studies submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

An example of a scenario in which such a situation may occur is where a health and safety study is originally submitted to EPA under FIFRA, but is subsequently used for TSCA purposes (e.g., in support of a TSCA section 6 risk evaluation) and where the health and safety study could have been collected under a TSCA authority (e.g., pursuant to TSCA section 8(d)). Under FIFRA section 10(g), the disclosure of such a study is limited to protect against disclosure to foreign or multinational pesticide producers, but if the study were submitted under TSCA, much of the information in the study would not be protected from disclosure under TSCA section 14(b)(2).

The potential for conflict between statutory data protection regimes, and the potential for disclosure of information originally submitted under the expectation of specified information protection requirements, has greatly increased from when the earlier regulations were promulgated. EPA recognizes that there are several options for dealing with these potential conflicts. As noted above, EPA is proposing that in certain circumstances some information obtained under authorities other than TSCA are information obtained under TSCA. EPA also seeks to ensure that when information is submitted to EPA under a statutory provision that provides an assurance of privacy, those privacy protections continue to apply even when the information is used for a different purpose. *Cf Food Marketing Institute v. Argus Leader Media*, 139 S.Ct. 2356, 2366 (2019) (acknowledging the importance of assurances of privacy to determinations regarding the confidentiality of information). Thus, EPA is proposing that when there is a conflict between statutory data protection regimes, the rules regarding the treatment of information in that statute under which the information was originally collected should continue

to apply to the information, regardless of how it is used by the Agency under TSCA. The proposed regulations establishing this approach to potential conflicts appear in proposed section 703.1. In addition, there are procedures in TSCA section 14 that would be appropriate to apply to such data, such as the limited disclosure authority, often under confidentiality agreements, that is provided by TSCA section 14(d).

Other alternatives on which EPA requests comment include the approach embodied in 40 CFR 2.202(d) that the statute which provides for the greatest disclosure of the information governs, or the opposite, that the most disclosure-restrictive statute governs. Either approach could be implemented by applying the most (or least) restrictive statute as a whole or by comparing specific statutory provisions with TSCA section 14 and applying the least (or most) restrictive provision on a provision-by provision basis. EPA believes that the approach presented in proposed section 703.1 strikes an appropriate balance and provides greater clarity, as well as being consistent with the disclosure requirements applicable when the submitter originally provided the information to EPA.

EPA requests comment broadly on these and any other options for addressing, minimizing, or eliminating conflict between provisions under different statutes regarding confidentiality, disclosure, and treatment of information, including but not limited to alternative statutory interpretations, principles that should govern the resolution of conflicts, and options for resolving specific conflicts. EPA specifically requests comment on whether the proposed approach appropriately balances transparency under TSCA while also ensuring appropriate protections for information obtained initially under another statute consistent with the assurance of privacy implicitly or explicitly provided by the government when such information is obtained. *See Food Marketing Institute v. Argus Leader Media*, 139 S.Ct. 2356, 2366 (2019).

EPA also specifically seeks public comment on the proposed scope of the rulemaking, particularly that information originally obtained without the use of a TSCA authority is nevertheless obtained under TSCA if the Agency has the authority to collect the information and

it was used for a TSCA purpose. EPA is also seeking comment on whether EPA needs to exercise its TSCA authority or invoke its TSCA authority in the original information collection in order for information to be covered by TSCA section 14. EPA also seeks public comment on the proposed treatment of information that was originally submitted under another statute, as well as the alternatives identified. EPA is particularly interested in comments on how studies that were originally submitted under FIFRA should be treated under the TSCA regulations.

Finally, EPA is interested in comments on whether and, if so, how the term “TSCA submission” should be defined in proposed section 703.3.

C. Requirements for Asserting a Confidentiality Claim

TSCA section 14(c) governs assertion of confidentiality claims for TSCA submissions. This provision requires that persons submitting information under TSCA substantiate most confidentiality claims at the time of submission. It also includes additional certification and generic name requirements. These and related requirements are elaborated upon in Unit III.C.

1. Assertion of confidentiality claim upon submission of information to EPA.

TSCA section 14(c)(1)(a) requires an affected business to assert a claim for protection from disclosure concurrent with submission of the information. Consistent with this provision, proposed section 703.5 would require that confidentiality claims be asserted at the time of submission. If no such claim is made, the information may be made available to the public without prior notice to the person who submitted the information. While similar language appears in some of the existing regulations that implement TSCA (e.g., 40 CFR 711.30(e)), this proposal would clarify that the up-front assertion requirement is applicable to all non-exempt TSCA CBI claims, in accordance with TSCA section 14(c)(1)(A).

Proposed section 703.5 would further clarify and reiterate that where a TSCA submission identifies a chemical substance listed on the confidential portion of the TSCA Inventory but does not assert a confidentiality claim for the chemical identity as required by TSCA section 14 or in the manner required by the applicable rule (see, e.g., 40 CFR 711.30), the specific chemical

identity would no longer be eligible for confidential treatment on the TSCA Inventory. This would not apply where the submission does not pertain to manufacture or processing for commercial purposes, e.g., research and development.

The TSCA Inventory is a list of chemical substances manufactured or processed for a commercial purpose. A substance may be afforded confidential Inventory treatment (e.g., listing by generic name and accession number) so long as the fact that anyone manufactures or processes that substance for commercial purposes in the United States has not been disclosed to the public. By making a non-confidential report of having manufactured or processed a particular substance, the reporter in effect discloses their activities concerning the substance to the public and renders the substance ineligible for continued confidential Inventory treatment. EPA would update the TSCA Inventory to publicly list the specific chemical name and Chemical Abstracts Service Registry Number (CASRN), if available, without further notice (to any person who may have made a CBI claim for this substance). (Updates to individual submissions that contain a prior claim for what appears to be the same information would occur only after that claim is withdrawn or as result of a review and final determination in accordance with TSCA section 14 denying the claim in that submission.) Under some existing rules, once the chemical identity is listed on the public portion of the TSCA Inventory, claims can no longer be asserted for such information (see, e.g., 40 CFR 711.30(a)(2)(i)). This is also intended to clarify that the Agency will not provide notice to submitters with previously approved or pending claims for the same chemical identity prior to such disclosure on the TSCA Inventory. 40 CFR 711.30(a)(2)(i)). In addition, other chemical identity CBI claims for the substance would likely be denied upon review. However, claims for information related to the chemical identity, e.g., the identity of the submitter, would not be precluded.

2. Substantiation and exemptions.

EPA previously published an interpretation concerning the requirement to substantiate CBI claims in TSCA section 14(c)(3), see (Ref. 6). In that document, EPA stated that the statute

requires persons asserting CBI claims to substantiate those claims at the time the affected business submits the claimed information to EPA. This proposed rule, in proposed section 703.5(b)(1), would make EPA's TSCA confidentiality regulations consistent with TSCA section 14(c)(3).

Subsequent to the interpretation that published in the *Federal Register* of January 19, 2017 (Ref. 6), some TSCA rules were updated to include a set of required substantiation questions and apply the substantiation exemptions in TSCA section 14(c)(2). See, e.g., Chemical Data Reporting at 40 CFR 711.30. This proposed rule includes a standard set of substantiation questions in proposed sections 703.5(b)(3) and (4) that would be applicable to any confidentiality claim in any TSCA submission for which substantiation is required and includes additional substantiation questions specific to chemical identity claims. However, proposed section 703.4(b)(3) would provide that individual TSCA rules may modify the questions (by, for example, not requiring answers to substantiation questions that are not applicable in a particular TSCA submission type).

The substantiation questions in proposed sections 703.5(b)(3) and (4) have been designed to elicit information to allow EPA to determine whether the submitter's claim for confidentiality meets the substantive review criteria set forth in proposed section 703.7(f). EPA is interested in public comment concerning the proposed question set, including whether some questions might be consolidated or revised to minimize burden while also assuring responses are adequate to support a confidentiality determination (i.e., according to the criteria in proposed section 703.7(f)). The questions proposed here are similar to those included in the 2020 amendments to the Chemical Data Reporting (CDR) rule (see 40 CFR part 711) which the Agency believes are adequate to support its review of confidentiality claims in those submissions.

a. Patents.

EPA is proposing a question on patents in proposed section 703.5(b)(3)(iii)(C) and is seeking comment on alternatives to the proposed question language, or whether a standalone

patent question is necessary at all. The Agency requests comment on whether a standalone patent question is necessary or if it can be reasonably added to the publications question found in proposed section 703.5(b)(3)(iii)(B). In the Agency's experience, patents related to information claimed as CBI under TSCA rarely if ever disclose information in the same context or with the same level of detail as in the related TSCA submission. The Agency notes that asking whether information *appears* in a patent is not the same thing as asking whether the information is *covered* by a patent. For the purposes of TSCA confidentiality claims, the Agency is interested in both whether the same information claimed to be confidential in the TSCA submission *appears* in a patent and whether it is *covered* by a patent. More specifically, if the exact same information appears in both a published patent and in the TSCA submission, then the information should not be entitled to confidential treatment. Also, if the information is covered (i.e., legally protected) by a patent in such a way that no substantial harm to the competitive position of the business would result from the release of the information, then the information is not subject to confidential treatment on that ground as well. If the question of whether TSCA information claimed as CBI can both appear in and be covered by a patent without destroying the CBI claim can *always* be answered with a yes or no response with no additional explanation, then a standalone patent question may not be necessary. The Agency seeks comment from submitters explaining why they believe existence of a patent that contains and covers the information claimed CBI should not affect the ability of the submitter to claim the same information as CBI under TSCA.

Alternatively, the Agency requests comment on whether the standalone patent question used in the 2020 CDR rule (40 CFR 711.30) and proposed section 703.5(b)(3)(iii)(C) is adequate, or whether can be improved to elicit more pertinent responses from submitters regarding the potential public disclosure in a patent of the information claimed confidential in the TSCA submission. The existing question is as follows: Does any of the information claimed as confidential appear in one or more patents or patent applications? If yes, provide the associated

patent number or patent application number (or numbers) and explain why the information should be treated as confidential.

Particularly, the Agency would like to know how a company would be reasonably likely to suffer substantial competitive harm if the information is released under TSCA if the company already enjoys legal protections against competitors for patent infringement. Further, should the patent question elicit substantiation to explain why the information claimed to be confidential in the TSCA submission is not actually revealed in the particular patent? The Agency proposes the following as an alternative substantiation question: Has a patent been published for the chemical identity you claim confidential? What chemical identity information is not revealed by the patent? How is release of that specific information likely to cause substantial competitive harm? Failure to explain this harm may lead to denial of your confidentiality claim.

The Agency requests comment on whether the proposed alternative question is more likely to elicit pertinent responses on the relevance of a patent and invites suggestions that may help improve how the Agency considers patents in its CBI reviews.

b. Trade secrets.

EPA has observed that the question concerning trade secrets found in several existing TSCA rules, e.g., at 40 CFR 711.30(b)(4), tends to elicit answers that are either redundant with the answers to other substantiation questions, or otherwise do not tend to include information that is useful for the agency to consider whether the information meets the specific legal standard for trade secrets. This is rooted in confusion about trade secrets and CBI, which are distinct but related concepts.

TSCA section 14(a) invokes FOIA Exemption 4 as a ceiling for protecting business information. Exemption 4 protects “trade secrets and commercial or financial information obtained from a person and privileged or confidential.” 5 U.S.C. 552(b)(4). Trade secrecy has long been held as grounds for Exemption 4 protection distinct from that for “commercial or financial information obtained from a person and privileged or confidential.” See, e.g., *Public*

Citizen Health Research Group v. FDA, 704 F.2d 1280, 1286 (D.C. Cir. 1983).

A trade secret has been defined by the D.C. Circuit as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen* at 1288. This definition also incorporates a requirement that there be a "direct relationship" between the trade secret and the productive process.

CBI is defined by 5 U.S.C. 552(b)(4) as information that is (a) commercial or financial, (b) obtained from a person, and (c) privileged or confidential. The U.S. Supreme Court has addressed the meaning of the word "confidential" in 5 U.S.C. 552(b)(4) stating that "confidential" must be given its "ordinary" meaning, which is information that is "private" or "secret." *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356, 2363 (2019). The Court held that at least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is "confidential" within the meaning of FOIA Exemption 4. *Food Marketing* at 2366. In addition, TSCA section 14 requires the submitter to demonstrate that it has a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the business.

While the trade secret standard and CBI standard could theoretically provide two avenues to protect information from disclosure, EPA is not aware of any situation where information submitted under TSCA was determined to be entitled to trade secret protection but not CBI protection. EPA does not believe that asking a specific trade secret question for TSCA confidentiality substantiations will generate useful information because of the considerable overlap between the two standards. EPA seeks comment on whether the trade secret question still has value in the context of TSCA confidentiality claims.

c. Specificity of competitive harm.

In order to properly evaluate the various CBI claims in a single submission, EPA needs a

separate explanation from the submitter for each type of information claimed as confidential to explain why disclosure of that information would be likely to cause substantial competitive harm. To that end, EPA proposes two versions of the substantiation question concerning substantial competitive harm in this rulemaking. The first version of the question comes directly from the CDR rule, which states: “will disclosure of the information claimed as confidential likely cause substantial harm to your business's competitive position? If you answered yes, describe the substantial harmful effects that would likely result to your competitive position if the information is disclosed, including but not limited to how a competitor could use such information, and the causal relationship between the disclosure and the harmful effects.” 40 CFR 711.30(b).

The second version for consideration is in proposed section 703.5(b)(3)(i): Please specifically explain what harm to the competitive position of your business would be likely to result from the release of the information claimed as confidential. How would that harm be substantial? Why is the substantial harm to your competitive position likely (i.e., probable) to be caused by release of the information rather than just possible? If you claimed multiple types of information to be confidential (e.g., site information, exposure information, environmental release information, etc.), explain how disclosure of each type of information would be likely to cause substantial harm to the competitive position of your business.

The version of the question in proposed section 703.5(b)(3)(i) may enable EPA to better determine whether disclosure of the information is likely to cause substantial harm to the competitive position of the submitter. For purposes of this question, the term “substantial” means “of considerable importance.” Oxford English Dictionary (2021). “Likely” means “probable.” Oxford English Dictionary (2021). The last portion of the question is intended to help submitters explain how each type of information claimed confidential could harm the business if released. For instance, the harm to the business that could result from release of a confidential chemical identity may be different from the harm that could result from release of information concerning

the number of workers exposed to the chemical during processing.

EPA requests comment from submitters and the public on which of the two proposed versions of the question would be most likely to elicit information from submitters that will best allow EPA to determine that the submitter has demonstrated a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of its business. EPA is also seeking comment on how “substantial” and “likelihood” should be defined.

d. Exemptions.

The proposed section 703.5(b)(5) addresses the TSCA section 14(c)(2) exemptions from the substantiation requirement. This proposed provision includes criteria for the exemption in TSCA section 14(c)(2)(G) pertaining to substances that have not been offered for commercial distribution. The other proposed exemptions include:

- Specific information describing the processes used to manufacture or process a chemical (e.g., information reported under 40 CFR 720.45(g)(2));
- Marketing and sales information (note that submitting company identifiers are not generally themselves considered marketing and sales information);
- Information identifying a supplier or customer (such as the identities of some joint submitters reporting information under 40 CFR 720.40(e) or 711.15);
- Details on mixture composition and percentage (such as might be included in a TSCA section 8(e) notice of substantial risk that concerns a mixture);
- Specific chemical substance use information (such as is required to be reported under 40 CFR 720.45(f) and 725.155(g)); and
- Specific production or import volumes (such as are required to be reported under 40 CFR 711.15 and 720.45(e)).

EPA expects to update the reporting forms and applications for most TSCA submissions to prompt the submitter for substantiation where required, but not to prompt the submitter for types of data the Agency has concluded are always covered by a substantiation exemption.

3. Public copies of submissions.

In proposed section 703.5(c), EPA proposes to require public copies of submissions that include confidentiality claims. The proposed rule would not require preparation of a separate public copy where the reporting form or electronic reporting application contains a specific CBI designation identifying specifically what is claimed as CBI. However, where the submission is made without the use of such a TSCA reporting form (e.g., subpoena responses), or includes attachments or other “non-fielded” data, the submitter would be required to produce and submit a public (sanitized) copy of the submission and/or attachments. Some existing TSCA rules already include such a requirement. See, e.g., 40 CFR 720.40(d)(2) and 716.55(b). This proposed rule would consolidate existing requirements in proposed new part 703 and extend them generally.

The proposed provision would also provide that the sanitized version would have to redact only that information that is claimed as confidential. Any information not included in the sanitized version, or redacted from the sanitized version, must be subject to a confidentiality claim and as such must be substantiated as described in this unit. It further states that a public copy that redacts all or substantially all of the original submission would most likely not meet the requirements of the rule because it is unlikely that all of the information in a form or attachment can be appropriately claimed CBI. Additionally, any information not included in or redacted from a public copy is subject to the supporting statement in TSCA section 14(c)(1)(B) and the certification requirement in TSCA section 14(c)(5). False statements may give rise to criminal liability under 18 U.S.C. 1001.

4. Supporting statement and certification.

TSCA section 14(c)(1)(B) requires that each claim of confidentiality be accompanied by a standard supporting statement regarding the eligibility of the information for confidential treatment. TSCA section 14(c)(5) also requires a certification that the TSCA section 14(c)(1)(B) statement and information required to substantiate the claim under TSCA section 14(c)(3) are true and correct. (See explanation in Unit III.A.2. of the preamble to the CDR rule (Ref. 7)). This

supporting statement and certification language has already been incorporated in most TSCA reporting forms (example available at <https://www.epa.gov/tsca-cbi/making-cbi-claims-tsca-submissions#howto>). To the extent that the submission is not being made on such a reporting form (e.g., a subpoena response), proposed section 703.5(a) provides language that may be included in a cover letter or other attachment to a submission.

5. Generic names.

TSCA section 14(c)(1)(C) requires the submission of a generic name any time a specific chemical identity is claimed as confidential. This provision further requires that the generic name be “structurally descriptive” and that it “describe the chemical structure [...] as specifically as practicable” while also protecting the features of the chemical substance that are claimed confidential or where disclosure would likely cause substantial harm. 15 U.S.C.

2613(c)(1)(C)(ii). The generic name must also be consistent with the generic name guidance developed in accordance with TSCA section 14(c)(4)(A), 15 U.S.C. 2613(c)(1)(C)(i). See Refs. 8, 9 and 10. The generic name guidance document provides information to assist companies in creating structurally descriptive generic names for chemical substances whose specific chemical identities are claimed confidential, for the purposes of protecting the specific chemical identities from disclosure while describing the chemical substance as specifically as practicable, and for listing substances on the TSCA Chemical Substance Inventory. The proposed rule acknowledges that the TSCA Inventory already includes generic names for confidential substances, and that in most cases, such generic names are expected to be acceptable for the purposes of compliance with TSCA section 14(c)(1)(C) (possible exceptions may include generic names for some substances added to the TSCA Inventory prior to June 22, 2016, which would be addressed under proposed section 703.5(d)(2)).

For substances that are not on the TSCA Inventory (e.g., new chemical submissions under TSCA sections 5 or 8(e) submissions concerning pre-market chemical substances), the proposed rule includes a few basic criteria, drawn mainly from the TSCA section 14(c)(4)(A)

guidance (e.g., the generic name should mask only the confidential portions of the specific chemical name, generally only one structural element of a specific chemical name may be masked to protect a confidential chemical identity), and would require that where the submitter believes those criteria are in some way inappropriate or inapplicable to a particular substance or generic name, the submission must also include an explanation for why more extensive masking of the specific chemical identity is necessary in the particular case.

In proposed section 703.5(d)(3), EPA is also proposing that where a generic name submitted for a substance that is not on the TSCA Inventory is acceptable for the purposes of meeting the requirements of TSCA section 14(c)(1)(C), the generic name might nonetheless be later subject to additional review and potential change when commercial manufacture of the substance is commenced (e.g., when a Notice of Commencement (NOC) is submitted). Further procedures and requirements for review and acceptance of generic names submitted with an NOC are elaborated in proposed revisions to 40 CFR 720.102 and 725.190, As discussed in Unit II.E.5.

Finally, in proposed section 703.5(d)(4), EPA is proposing to provide an opportunity to revise proposed generic names that EPA concludes are not in compliance with 15 U.S.C. 2613(c)(1)(C). EPA would provide an electronic notice of the deficiency to the submitting company, who would then be afforded ten days to propose a revised generic name. If the submitter does not submit a compliant generic name, EPA would reject the underlying submission and may ultimately deny the CBI claim. (See discussion in Unit III.C.4. and proposed section 703.5(e) on deficient submissions.)

6. Deficient submissions.

In proposed section 703.5(e), EPA is proposing to specify that confidentiality claims, identified for review pursuant to proposed section 703.7(a), that are missing the certification, substantiation, or generic name (where applicable) required by TSCA section 14(c) will be considered deficient. Submissions that are missing a public copy or where the public copy does

not meet the requirements of proposed section 703.5(b)(6) would also be considered deficient- EPA has observed many instances where the attachments to TSCA submissions appear over-redacted (e.g., public copies of health and safety studies or the Safety Data Sheets (SDSs) that are often provided with TSCA section 5 PMN submissions might be entirely or largely blank). This level of redaction is rarely if ever consistent with the limitations that TSCA section 14(b) places on CBI protections for health and safety information. Submissions that include a generic name that does not meet the requirements of proposed section 703.5(d) or rely on inappropriate substantiation exemption assertions would also be considered deficient.

EPA anticipates that electronic reporting requirements, coupled with modifications to new and existing reporting forms to incorporate the certification statements and prompt for substantiation and generic names, will eliminate most such deficiencies. However, to the extent TSCA submissions are occasionally still made on paper or are not made using a TSCA form for which entries can be automatically validated (e.g., unformatted information in attachments to TSCA forms, such as health and safety study reports or SDSs), such deficiencies may still occur. EPA is proposing that when such deficiencies are identified, EPA would initially place a hold on the submission.

In such an instance, EPA would provide notice of the deficiency to the submitter and provide them with a ten (10) business day opportunity to fix the deficiency. Meanwhile, any applicable review periods for the underlying submission and for the confidentiality claim would be suspended while the hold is in place. For example, if EPA held a PMN for an inadequate public copy, both the CBI review period and the 90-day review period for the PMN would be suspended until either (1) the deficiency in the CBI claim is remedied, or (2) ten (10) business days pass without the deficiency being remedied.

If the deficiency is not remedied within ten (10) business days of EPA providing the notice of deficiency, EPA will resume the review of the submission and will likely deny the CBI claim(s).

EPA is interested in public comment on this approach to claim deficiencies, and on alternative approaches, such as strictly interpreting the requirements of TSCA section 14(c) as necessary to making a valid confidentiality claim (i.e., claims that don't meet the requirements of TSCA section 14(c) would not be recognized, and could thereby be released to the public without prior notice to the submitter). Additionally, EPA is not proposing a time window in which the Agency may identify deficiencies, which potentially leaves open the possibility that a deficiency is identified, for example, on day 45 of the review period for the underlying submission. EPA is particularly interested in public comment on whether a time period for identifying deficiencies, e.g., between 10 to 15 business days from the date of submission, would be appropriate.

7. Electronic reporting.

Most TSCA submissions must now be made electronically, using various reporting tools built into CISS (Chemical Information Submission System, EPA's web-based reporting tool for preparing and submitting TSCA submissions) and submitted via EPA's CDX system (Central Data Exchange, EPA's centralized electronic document reporting portal). The proposed section 703.5(f) would fill most of the current gaps in electronic reporting requirements by requiring that nearly all TSCA confidentiality claims be asserted electronically. For example, while current TSCA section 8(e) notices of substantial risk may be made either on paper or via an optional electronic reporting form, EPA is proposing that all TSCA section 8(e) notices that include a confidentiality claim would be required to be submitted electronically, using an EPA-provided reporting tool. Similarly, electronic reporting applications would be developed or updated for TSCA section 12(b) notices of export and TSCA section 5 polymer exemption notifications. Means of providing information via CDX relating to TSCA section 6 prioritization, risk evaluation, and risk management have already been made available. These new and updated reporting applications would be available by the time the new electronic reporting provisions become effective. This proposal would expand the electronic reporting requirement to all TSCA

section 12(b) notices of export and TSCA section 5 polymer exemption notifications (whether or not they include confidentiality claims), thereby closing most remaining gaps in electronic reporting requirements under TSCA. A discussion on the benefits of electronic reporting under TSCA relevant to the expansion described in this proposed rule was provided in a previous document (Ref. 1). Some exceptions to the general requirement to report CBI-containing materials electronically will remain, such as for materials that EPA has subpoenaed or requested or collected in the course of a TSCA inspection, which may be collected in person, and/or in a format or volume that makes electronic submission impractical.

Closing these gaps in electronic reporting is intended to reduce the likelihood of submitter error when asserting a confidentiality claim, facilitate EPA's ability to review confidentiality claims in a timely manner, reduce resources required to process, handle, and store TSCA submissions, reduce the opportunity for errors related to the handling of CBI, facilitate public access to information not claimed as CBI, and enable or enhance EPA and TSCA submitters' ability to promptly communicate about the status of confidentiality claims in the submission in the future. EPA will enhance its current practice of assigning a document or "case" number to each TSCA submission (e.g., P-20-0XXX or 8EHQ-2020-0XXXX) by assigning and making that submission identifier available to the submitter within the submitter's CDX account.

As stated above, EPA is proposing to require any information or materials not obtained under TSCA section 11 to be submitted through CDX if they contain a TSCA CBI claim. The Agency is requesting public comment broadly on this approach, and on whether there are scenarios the Agency should consider where a person providing TSCA CBI to EPA via an irregular means (e.g., a letter) would not be able to or would face substantial difficulties in using CDX to submit information claimed CBI.

8. Requirement to report health and safety information using harmonized templates.

In proposed section 703.5(g), EPA is proposing a requirement to provide health and safety studies and information from health and safety studies in a templated format, using

Organisation for Economic Co-operation and Development (OECD) Harmonized Templates, where an applicable template is available. See <https://www.oecd.org/ehs/templates/harmonised-templates.htm>. EPA is interested in comment on this proposed requirement. Many TSCA submitters may be familiar with and already have created templated versions of health and safety study reports they may be required to submit under TSCA, owing to reporting requirements in other countries. For these submitters, the burden associated with this requirement to submit templated data is expected to be minimal. EPA anticipates that data that has been put into one of these standardized templates will be more readily used and shared within the Agency, and (where permitted by confidentiality restrictions and other agreements) across jurisdictions. In addition, CBI claims may be more clearly indicated if asserted via a templated format (e.g., CBI claims could be indicated by checking a box for each discrete data element, rather than by redacting sections of text piecemeal from a study report line by line). It should be noted, however, that the proposed requirement to provide data in a templated format does not supersede existing regulatory requirements to also submit a full study report, such as the present requirement for TSCA section 4 test reports.

EPA is soliciting public comment on the proposed requirement that information obtained from a study, in addition to whole study submissions, be provided in templated form to the Agency. EPA is also interested in public comments on the requirement that submitters identify the “appropriate” OECD template for a particular submission.

9. Maintenance of company contact information and communications concerning claims.

From time to time, EPA needs to contact a company about CBI claims made in a TSCA submission. These contacts may be made relatively soon after submission, in order to clarify something about a claim or provide an opportunity to correct a deficiency with the claim (see proposed section 703.5(e)), or they may be required notifications made months or years later, such as a notice concerning a denied confidentiality claim, or a notice concerning a pending confidentiality review under TSCA section 14(f). In the future, EPA will also need to contact or

notify companies about expiring confidentiality claims, pursuant to TSCA section 14(e). For all of these reasons, it is important for EPA to have current contact information for the submitter of each TSCA submission and an efficient means for satisfying the notice requirements under the statute. EPA is proposing to require companies to maintain current contact information for all individuals associated with a submission (which reinforces and complements existing CDX terms and conditions concerning maintenance of CDX accounts, particularly the requirement to notify EPA when individual account access is no longer needed so that the account can be deactivated; see <https://cdx.epa.gov/Terms>), enhance the means by which companies update contact information, and require the submission of notices of transfer of ownership via CDX.

In light of the significant resources and document tracking concerns related to continuing to largely rely on paper correspondence for such communication and notifications, the rulemaking proposes that most such correspondence would be electronic, via CDX. See proposed section 703.5(h). “Two-way” communication via CDX provides a secure means for EPA and companies to correspond about a TSCA submission or confidentiality claims. EPA can more readily assure that a communication is available to a company or specific submitter by using CDX to communicate, rather than certified mail or a courier. In CDX, EPA is able to verify that a particular communication is available to the submitter of a particular submission and is able to track the date the communication was sent. EPA believes that these facts satisfy the requirement in TSCA section 14(g)(2)(A) that notification, including for the denial of a confidentiality claim, be sent by means that “allows verification of the fact and date of receipt.” This would be the case even if EPA does not receive a “read receipt” or cannot otherwise verify that the submitter opened the electronic notice, much as EPA cannot verify whether or when a recipient of certified mail opens the envelope and reads the contents.

The proposed rule describes how EPA expects to furnish the required notices concerning expiration of confidentiality claims under TSCA section 14(e). The first expirations will occur in 2026, for claims that were asserted in 2016 and that were not exempt from substantiation and

review according to TSCA sections 14(c)(2) and 14(g). As proposed, EPA would periodically publish a list of TSCA case numbers that are approaching claim expiration on the EPA website, or other appropriate platform. In addition, EPA intends to send individual notices of upcoming claim expiration and other individual notices concerning CBI claims to the company via CDX.

The proposed rule includes similar notice and communication provisions for when review of claims is initiated under TSCA section 14(f) (e.g., in response to a FOIA request for information that has been claimed as confidential). EPA would provide any necessary notice of review and/or opportunity to substantiate or resubstantiate to the Authorized Official or Technical Contact listed on the most recent version of the submission (or as listed in a more recent notice of transfer of ownership relating to that submission), along with instructions for response. Alternatively, if the submission with the relevant CBI claim is not associated with a CDX account, EPA would send the notice via CDX to the company contact provided in the most recent TSCA submission made by that company.

For TSCA submissions that were not originally made via CDX, EPA is proposing to send the notice by certified mail or courier to the address provided in the most recent TSCA submission from that company, or via other means that allows verification of the fact and date of receipt. For example, EPA is also considering further development of two-way CDX communication to permit EPA to also send these notices, likely using the contact information in the most recent CDX submission from the same company.

10. Withdrawing claims.

TSCA confidentiality claims may be voluntarily withdrawn by the submitter at any time. *See* 15 U.S.C. 2613(e)(1)(A)(i) and (B)(ii)(I). Proposed section 703.5(i) includes instructions for voluntarily withdrawing confidentiality claims prior to automatic expiration or denial. The preferred approach is for the company to amend the submission electronically, via CDX, to withdraw the claims (i.e., “uncheck” the CBI boxes or unredact the submission and resubmit it). When this is not possible (for example, when the submission was not originally submitted via

CDX, or because the company does not have access to the electronic submission), claims may be withdrawn by CDX submission as well, using a new correspondence tool that enables efficient linking of the withdrawal letter with the related submission, and permits EPA to communicate with the company about the withdrawal (e.g., if clarification is needed).

11. Amending a public copy following claim denial or expiration.

Following the denial or expiration of a confidentiality claim, the public copy of the submission must be revised to provide public access to the newly non-CBI information. For some electronic submissions this may be a more or less straightforward process of un-checking some boxes and generating a new public copy of the submission, but for other TSCA submissions, the denied or expired claims may be intermingled with still-valid or approved claims, or the claims may have been indicated by numerous redactions throughout a voluminous text. The proposed rule (see proposed section 703.5(j)) would encourage companies to prepare this updated public copy themselves. EPA believes that submitters are in the best position to assert and indicate their remaining claims accurately. However, in the case that the submitter is unavailable or otherwise unable to update the public copy, the proposed rule makes clear that EPA will undertake this function, as needed.

EPA invites comment on the option of requiring TSCA submitters to update their original submission to reflect CBI claims that have been withdrawn or denied.

D. EPA Review of Confidentiality Claims

1. Representative subset.

TSCA section 14(g)(1)(A) requires that EPA approve or deny confidentiality claims, except for claims exempt from review under TSCA section 14(c)(2). TSCA section 14(g)(1)(C) further specifies that EPA review all confidentiality claims for chemical identity (except those exempt under TSCA section 14(c)(2)(G)) and a “representative subset” comprising at least 25% of all other claims, with the exception (as provided in TSCA section 14(g)(1)(A)) of information exempted from substantiation under TSCA section 14(c)(2).

Proposed section 703.7 would codify EPA's current practice of reviewing all claims (except those exempt from substantiation requirements under TSCA section 14(c)(2)) in every fourth submission received via CDX that contains CBI claims besides those pertaining to chemical identity.

Consistent with current practice, submissions with CBI claims not submitted through CDX would be excluded from the representative subset. As explained above, all submissions other than those submitted pursuant to TSCA section 11 will be required to be submitted through CDX (see proposed section 703.5(f)), so the Agency believes that only a small number of infrequent TSCA submissions would not be included in the total number of claims received for purposes of determining the representative subset. Moreover, these materials are not representative of TSCA submissions because they are collected irregularly, from widely spread geographic locations, may be voluminous, provided in multiple batches, be of assorted media type (photos, large maps, etc.) or exist only on paper or other physical media at the time of collection. EPA is also proposing that amendments to submissions would not be counted as new submissions for purposes of selecting the representative subset—rather, the confidentiality claim review will include amendments available at the time of review. EPA is interested in public comment concerning its selection of the representative subset, including possible alternative representative selection methods.

EPA is proposing that two additional types of submissions not be included in the representative subset as they are not representative of TSCA submissions as a whole. These include: (1) Bona fide inquiries under 40 CFR 720.25, and 721.11 and (2) TSCA section 5 prenotice communications (correspondence submitted prior to a prospective TSCA section 5 submission asking questions or requesting a meeting to discuss whether and how a prospective TSCA submission should be made). These document types are not representative of TSCA submissions as a whole. These submission types help submitters ascertain whether a TSCA submission is required in a particular situation and/or what type or format should be used to

make a particular submission. Moreover, in each case in which EPA confirms that a specific TSCA submission is required, these pre-notice or bona fide submissions would be followed by the corresponding TSCA submission, which itself would be subject to selection as part of the representative subset (e.g., a PMN or Significant New Use Notice). Conversely, where no TSCA submission is deemed necessary, the information in these documents does not relate to EPA's regulation of chemical substances under TSCA.

EPA is interested in public comment concerning the universe of claims that contribute to the representative subset and its identification of, and exclusions from, the representative subset, including possible alternatives.

2. EPA review of claims.

a. Procedures.

EPA is proposing to revise EPA's procedures for reviewing confidentiality claims. As noted in previous EPA statements (e.g., Ref. 6), EPA reviews confidentiality claims in accordance with the requirements in TSCA section 14 and has relied to date on the review procedures set out in 40 CFR part 2 for all TSCA CBI reviews. However, the review procedures described in 40 CFR part 2 (including TSCA-specific provisions at section 2.306), which were promulgated prior to the Lautenberg amendments, do not fully accommodate or account for the requirements in TSCA section 14, particularly the demands of the TSCA section 14(g)(1) mandatory review program. Rather than extensively update the EPA review procedures for TSCA CBI in 40 CFR part 2 to reflect the amendments to TSCA section 14, this rulemaking proposes to consolidate most of them in the proposed new part 703, consistent with the broader effort to centralize regulations on TSCA CBI.

In many respects, the procedures and substantive review criteria in proposed new part 703 mirror those in 40 CFR part 2 but include adaptations to reflect the requirements of TSCA section 14, and to facilitate the high volume, time-limited review process required to meet the requirements of TSCA sections 14(e) and 14(g). For example, the substantive criteria in 40 CFR

2.208, as referenced and modified by 40 CFR 2.306(g), would be retained, but would be somewhat modified to align with the substantial competitive harm language in TSCA section 14. (The other criteria include that the CBI claim has not expired, been waived, or withdrawn; that the business protects the confidentiality of the information; and that no statute prohibits confidential protection.)

The criteria would also be revised to clarify that whether a substance may be readily reverse engineered is among the factors EPA considers as part of the criterion on whether the CBI-claimed information is legitimately and reasonably obtainable without the business's consent. Alternatively, the Agency could consider whether a substance may be readily reverse engineered as a stand-alone criterion. The Agency requests comment on how this reverse engineering component should be incorporated into the Agency's substantive review criteria in proposed section 703.7(f), either as a stand-alone review criterion or as part of the existing criterion. The substantive review criteria in proposed section 703.7(f) will establish the Agency's standard of review for all TSCA CBI claims. For each claim to be approved, submitters' substantiations would be required to adequately address all of the criteria set forth in proposed section 703.7(f). Accordingly, the Agency would then be able to deny TSCA CBI claims for failure to address any one of the proposed criteria in the substantiation.

The requirement in 40 CFR 2.306(e)(1) that EPA's Office of General Counsel (OGC) make most final confidentiality determinations would no longer be required by regulation under the proposed new part 703; rather, final determinations may be made by OGC or other EPA offices (e.g., the EPA Office of Pollution Prevention and Toxics), as designated by the General Counsel. Regardless of which office within EPA issues a given final determination, EPA expects to continue to publish final CBI determinations on its website.

EPA also proposes, in proposed section 703.7(g), to add a means to request reconsideration by OGC of determinations denying confidential treatment. Reconsideration would be available during the 30-day notice and appeal period prior to disclosure of the

information. This mechanism is intended to permit parties to identify any EPA errors in the determination prior to the point that the information is disclosed, and without immediately proceeding to judicial review of the decision. If a request for reconsideration is timely received, EPA will suspend the 30-day notice period described in proposed section 703.7(e) while OGC reconsiders the Agency's determination. OGC will review the submission *de novo* and will only consider the submission record as it existed for the final determination. EPA requests comment on this reconsideration approach and the suspension of the 30-day notice period.

The proposed rule sets forth review procedures to apply to CBI reviews initiated under TSCA section 14(g)(1) (including reviewing requests for extension under TSCA section 14(e)) as well as some additional procedures to implement CBI reviews initiated under TSCA section 14(f). In proposed section 703.7(b)(2), EPA proposes to permit submitters requesting extension of confidentiality protections under TSCA section 14(e) to either submit new substantiation or rely on substantiation that was provided with the initial submission, certifying that the substantiation remains true and correct.

In proposed section 703.8, EPA proposes similar procedures for reviews initiated under TSCA section 14(f) as for those under TSCA section 14(g), though the notice and resubstantiation provisions necessarily vary to reflect the fact that the review of different claims may be triggered by TSCA section 14(f) versus TSCA section 14(g). The proposed rule also clarifies that EPA is not required to review claims as designated in TSCA section 14(f)(1) (claims concerning active or TSCA section 6(b) high-priority substances or where disclosure would assist EPA in conducting a risk evaluation under TSCA section 6); rather, reviews of such claims are discretionary.

The proposed rule also elaborates on the timing and scope of review in proposed section 703.7(c). For the purposes of TSCA section 14(g), the proposed rule specifies that the 90-day review period begins on the day EPA accepts a new TSCA submission that includes confidentiality claims (TSCA submissions under TSCA section 5 must clear a brief "pre-screen"

review for basic completeness to ensure consistency with requirements in 40 CFR part 720, which is usually complete within a few days of submission; following that review, the submission is considered “accepted”), and that amendments to non-chemical identity information in the submission will be considered in the confidentiality review for that submission up to 60 days after the original submission date. (New confidentiality claims concerning chemical identity would be reviewed within 90 days of EPA accepting the submission or amendment including the new chemical identity claim.) The date that the submission is considered “accepted” will be used to calculate the 10-year sunset period for purposes of TSCA section 14(e). “Accepted” is defined in the proposed section 703.3.

EPA notes that some submission types are often amended one or more times after submission (e.g., new chemical-related submissions under TSCA section 5) as new information is developed, or as requested by EPA. In order to meet the 90-day statutory review deadline, EPA believes it is important that submissions be complete, at least procedurally, prior to starting review, and notes that there is a point in the 90-day period past which significant amendments to the submission and related claims would be difficult or impossible to consider while still meeting the statutory review deadline.

EPA has considered some alternatives in developing this proposed rule, including either resetting the 90-day clock every time an amendment is received, or not commencing confidentiality claim review at all until some period of time after initial submission, to allow for a majority of amendments to be made prior to beginning the confidentiality review. In the first case, EPA identified that resetting the 90-day clock with each amendment would likely require a lot of duplicative effort. EPA also anticipates that either of these options would often delay confidentiality determinations considerably, especially for new chemical submissions, in which public interest has been heightened in recent years. EPA invites public comment on the proposed approach described in proposed section 703.7(c), as well as these and other alternatives.

b. Substantial competitive harm.

In the preamble of the 2020 final rule on CDR (Ref. 7), EPA noted that the Agency did not view the Supreme Court’s decision in *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356, 2363 (2019) as necessitating the Agency to remove the “substantial competitive harm” substantiation question for TSCA CBI claims. See also Ref. 11. Congress amended TSCA section 14 in 2016 to, among other things, specifically require any person asserting a CBI claim under TSCA to include a certified statement that the person has “a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person.” TSCA section 14(c)(1)(B)(iii) and (c)(5); see also TSCA section 14(c)(1)(C)(ii)(II) (referencing substantial competitive harm). For each claim, the Agency’s review will determine whether the business has made a satisfactory showing that it has a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the business.

The proposed rule clarifies that the Agency requires the certification statement on substantial competitive harm and considers substantial competitive harm as part of its substantive review criteria for TSCA CBI claims.

c. Information from health and safety studies.

The proposed rule also elaborates on the limitations on confidentiality protections for health and safety information described in TSCA section 14(b). TSCA section 14(b)(2), which denies confidentiality protection to health and safety studies and information from health and safety studies, excludes from its coverage certain categories of information in health and safety studies, such as formulas. In addition, existing regulations allow withholding of specified information beyond that provided in TSCA section 14(b)(2). See, e.g., 40 CFR 720.90(3) (allowing withholding of “[i]nformation which is not in any way related to the effects of a substance on human health or the environment, such as the name of the submitting company, cost or other financial data, product development or marketing plans, and advertising plans”). However, the applicable regulations are not uniform in this respect; nor has the statutory basis

for these provisions (which itself has changed under the Lautenberg amendments) been previously enunciated by EPA. The Agency is proposing here to systematize these provisions, generally allowing CBI claims for very limited categories of information contained within a health and safety study.

While such ancillary information may be contained in a study document submitted under TSCA, EPA does not consider such information to be part of a “health and safety study” as defined in TSCA section 3(8). That definition states that the term ‘health and safety study’ means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter. This definition does not seek to provide an exclusive list of what is or is not “included” in the health and safety study but instead clarifies that all “underlying” information must be considered part of the study. The term “underlying” is an adjective “used to describe something on which something else is based.” Cambridge Dictionary (Online). A study report may contain information beyond that which is the basis for the study. Information such as the names of lab technicians neither form the basis for the study nor are relevant to the study results.

Additionally, TSCA section 14(b)(1) provides that information that is protected from disclosure under this section, and which is mixed with information that is not protected from disclosure under this section, does not lose its protection from disclosure notwithstanding that it is mixed with information that is not protected from disclosure. TSCA section 14(b)(1) is consistent with the interpretation that a study report can contain information not included within the definition of a “health and safety study” under TSCA section 3(8) and adopting such an interpretation gives effect to TSCA section 14(b)(1).

EPA is therefore proposing a definition of “health and safety study” (for purposes of this proposed rule) in proposed section 703.3 that specifies types of information that are not within the scope of TSCA section 3(8):

- Name of the submitting company;
- Name of the laboratory;
- Internal product codes;
- Names of laboratory personnel;
- Names and other private information included in study data or reports;
- Cost or other financial data; and
- Product development, advertising, or marketing plans.

The Agency is requesting comment on the underlying interpretation and this list.

This proposed rule would clarify these existing provisions and make them uniform for all TSCA submissions. EPA invites comment on the proposed examples of information that might be in a study, but nonetheless permissible to withhold as confidential, should the information otherwise meet the confidentiality criteria in TSCA section 14.

E. Related or Corresponding Revisions to Other TSCA Rules

In addition to proposing a new confidentiality claim section of the TSCA rules, the proposed rule would revise confidentiality provisions in existing rules. In some cases, the proposed revisions would replace existing provisions with a cross reference to the proposed new part 703. In others, more specific and extensive revision is proposed.

1. Proposed revisions to 40 CFR parts 702, 704, 707, 716, 717, 723, and 790.

EPA is proposing to revise the following provisions to reference the general CBI provisions in the proposed new part 703:

- 40 CFR 702.37(d), the confidentiality provisions for manufacturer requests for risk evaluations;
- 40 CFR 704.7, the confidentiality provision for TSCA section 8(a) rules;

- 40 CFR 707.75(d), the confidentiality provision of rules concerning TSCA section 12(b) notices of export;
- 40 CFR 716.55, the confidentiality provisions for TSCA section 8(d) reporting rules;
- 40 CFR 717.19, the confidentiality provision for TSCA section 8(c) recordkeeping and reporting rules;
- 40 CFR 723.50(l) and 723.250 (f), the confidentiality provision for certain exemption requests under TSCA section 5 (low volume exemption and low releases and low exposures exemption); and
- 40 CFR part 790, the confidentiality provision of rules concerning TSCA section 4 test rules, orders, and agreements.

2. Further clarification proposed for 40 CFR part 707.

EPA is proposing to revise the provision concerning the contents of TSCA section 12(b) notices of export, 40 CFR 707.67(a), by adding a sentence to provide that in most cases, a confidential specific chemical identity need not be included in the notice (the primary exception would be in the case where the substance to be reported under TSCA section 12(b) is claimed as confidential but does not have a TSCA accession number). Instead, the TSCA section 12(b) notice of export may identify the substance by the generic name and accession number that appeared in the TSCA section 4, 5, 6, or 7 action that triggered the TSCA section 12(b) reporting requirement. EPA anticipates that with this change, TSCA section 12(b) submitters would submit fewer confidentiality claims for specific chemical identity, which in almost all cases is unnecessary to report under the existing TSCA section 12(b) rules.

3. Proposed revision in 40 CFR 717.17 and 723.250 to reflect electronic reporting.

EPA proposes to modify 40 CFR 717.17 and 723.250(f) to reflect the proposed new electronic reporting requirement discussed in Unit II.C.5.

4. Proposed revisions to confidentiality provisions in the PMN rules.

EPA is proposing to simplify and replace many of the confidentiality provisions in 40

CFR part 720, subpart E with a cross reference to the general confidentiality provisions in proposed new part 703. The general provisions on confidentiality in PMNs, 40 CFR 720.80, is proposed to be replaced with this cross reference. Requirements in 40 CFR 720.85 and 720.90 are proposed to be deleted, with portions moved to 40 CFR part 720, subpart F, the provisions concerning NOCs.

The existing provisions concerning chemical identity claims in PMNs and in health and safety studies would be covered in the proposed new part 703. In addition, TSCA section 14(c)(2)(G) created an exemption from the substantiation requirement for confidentiality claims for chemical identity when identity information is submitted before substance is offered for commercial distribution. The CBI claim review provisions of TSCA section 14(g) exclude these exempt claims from routine EPA review requirements, diminishing the need to elaborate on requirements for asserting and maintaining such claims in the PMN rules.

Relatedly, a confidentiality claim review process in existing 40 CFR 720.90, whereby claims that were made in health and safety studies in the PMN are revisited at the NOC stage, is a poor fit with new TSCA section 14(g) requirements that confidentiality claims be reviewed within 90 days of receipt, or in accordance with the discretionary or mandatory provisions of TSCA section 14(f). In practice, PMNs and NOCs (the latter of which may be submitted many months or years after the corresponding PMN, if at all) are treated by EPA as separate submissions for the purposes of routine CBI review. At the PMN stage, chemical identity claims, including claims made in health and safety studies, are generally exempt from review, per the exemptions from substantiation and review set out in TSCA sections 14(c) and (g). NOCs, on the other hand, do not include health and safety information. With the proposed deletion of 40 CFR 720.90, the review of confidentiality claims in NOC submissions would be limited to the information included in the NOC submission—principally chemical identity and submitting company information. Claims that were made in the PMN submission may be revisited at a later time, in accordance with either mandatory or discretionary review provisions in TSCA section

14(f).

5. PMN NOC provisions.

The proposed rule leaves much of 40 CFR part 720, subpart F, intact, but reorganizes some provisions that concern specific chemical identity claims in or following submission of an NOC. These provisions are presently in subpart E and would move to subpart F. Additionally, the proposed revisions would update and clarify NOC reporting instructions in 40 CFR 720.102(c)(2), concerning the assertion and substantiation of confidentiality claims throughout the NOC reporting form. The existing rule only reflects the substantiation requirements that predated the Lautenberg amendments, which were limited to specific chemical identity confidentiality claims, and do not reflect the newer generic name and certification requirements in TSCA section 14(c).

Revisions include adding a new paragraph (e) in 40 CFR 720.102, the substance of which is currently in 40 CFR 720.85(b)(3), concerning requirements that apply when asserting a confidentiality claim for chemical identity in the period after commencing commercial manufacture. Additionally, there is a cross-reference to the requirements of proposed new part 703, which, among other things, would replace the list of substantiation questions currently in 40 CFR 720.85 (which under existing rules, only apply to chemical identity claims in NOCs).

Finally, the proposed revisions to 40 CFR 720.102 would include a new paragraph (f), concerning generic names. These provisions are intended to be consistent with generic name provisions in proposed new part 703, but include some additional provisions specific to the submission and review of generic names for the purposes of listing on the TSCA Inventory, including additional procedures intended to aid the prompt negotiation by the submitter and EPA of more difficult generic names (which are themselves based in part on procedures presently in 40 CFR 720.85), and a provision that NOCs will be temporarily held in situations where the submitter has not provided an acceptable generic name despite the negotiation. If the submission is not corrected, EPA would proceed with review of the CBI claim for chemical identity and

would likely deny the claim. EPA invites comments on these and other possible approaches to efficiently developing an acceptable generic name for purposes of listing on the TSCA Inventory.

6. Microorganisms.

EPA is proposing to replace much of the confidentiality provisions currently in 40 CFR part 725, subpart C, with a new, simplified subpart C, which largely relies on a cross-reference to the proposed new general confidentiality provisions to be placed in proposed new part 703. The proposed amendments would remove current provisions that are inconsistent with the Lautenberg amendments, such as existing requirements to provide upfront substantiation of organism identity confidentiality claims prior to the commencement of commercial manufacture. The proposed rule also proposes some adjustments to the general confidentiality provisions in proposed new part 703 when they are applied to genetically modified microorganisms and other products of biotechnology covered by 40 CFR part 725. These include some adjustments to the substantiation questions to reflect some practical differences between these products and other types of TSCA chemical substances.

The proposed rule also includes proposed revisions to 40 CFR 725.190, concerning NOCs, that are similar to the proposed revisions to the parallel conventional chemical NOC provisions in 40 CFR 720.102, including some elaboration on what must be included in a generic name. As in the case with NOCs relating to PMNs, EPA proposes to update 40 CFR 725.190 to be generally consistent with generic name provisions in proposed new part 703, but with some additional provisions specific to the review of generic names for the purposes of listing on the TSCA Inventory, including additional procedures intended to aid the prompt negotiation of more difficult generic names, and a provision that NOCs will be held in situations where the submitter has not provided an acceptable generic name despite the negotiation (and that such deficiencies, if not promptly corrected, may result in denial of the claim). EPA invites comments on these and other possible approaches to efficiently developing an acceptable generic name for purposes of

listing on the TSCA Inventory.

7. Changes in proposed regulations.

This action proposes a significant number of new and revised CBI provisions to be included in proposed new part 703 and proposes to revise confidentiality provisions in other existing regulatory provisions to cross reference the proposed new part 703. EPA recognizes that during the pendency of this rulemaking process, EPA is developing other rulemakings that may address confidentiality provisions. For example, EPA is developing a proposed rule regarding asbestos reporting under TSCA section 8(a). Until this CBI rule is finalized, however, additional regulations proposed or finalized need to refer to the existing CBI regulations, rather than to the new and revised CBI provisions addressed in this rulemaking. EPA requests comment on options for harmonizing such provisions. Specifically, EPA requests comment on using this action to make any needed conforming amendments, e.g., adding cross references to the new and revised CBI provisions proposed here to any CBI provisions finalized during the pendency of this action including any CBI provisions finalized in the asbestos TSCA section 8(a) rule.

III. Request for Comments

EPA is seeking public comment on all aspects of this proposed rule and the Economic Analysis prepared in support of this proposed rule (Ref. 2). In addition to specific requests for comment included throughout this document, EPA is interested in comments pertaining to specific issues discussed in this unit. EPA encourages all interested persons to submit comments on the issues identified in this proposed rule and to identify any other relevant issues as well. This input will assist the Agency in developing a final rule that successfully addresses information needs while minimizing potential reporting burdens associated with the rulemaking. EPA requests that commenters making specific recommendations include supporting documentation where appropriate. EPA invites specific comment on:

- EPA's interpretation of the coverage of TSCA section 14(a) (proposed section 703.1), and how this may impact submitters of information to the Agency under other statutes, such as

FIFRA. EPA is particularly interested in comments on the treatment of FIFRA studies on inert ingredients under TSCA section 14(b)(2).

- The applicability of the proposed new or revised requirements to submissions received before the effective date of the subsequent final rule. Specifically, EPA requests comment on whether each proposed new or revised requirement should apply only to submissions received on or after the effective date of the final rule; to all submissions received on or after the effective date of the Lautenberg amendments; or to all submissions regardless of submission date.

- The proposed substantiation questions (proposed section 703.5(b)), especially the proposal to omit a trade secrets-specific question; on how the patents question might be modified to elicit more pertinent information; and comment on the alternative substantial competitive harm question.

- The proposed list of information that might be included with health and safety information, but that might be permissible to withhold as confidential (proposed section 703.5(b)(6)). EPA is also interested in comment on alternatives to the proposal that might better assure that health and safety information is not inappropriately treated as confidential.

- The proposed approach to CBI claim deficiencies (proposed section 703.5(e)) and on alternative approaches.

- Whether submitting templated data should be required (proposed section 703.5(g)).

- The option of requiring TSCA submitters to update their original submission to reflect CBI claims that have been withdrawn or denied (proposed section 703.5(j)).

- Selection of the representative subset, including possible alternative representative selection methods (proposed section 703.7).

- Whether bona fide or pre-notice inquiries or correspondence should be considered part of a representative subset of TSCA submissions (proposed section 703.7).

- On the proposed approach to determining when a TSCA section 14(g) CBI review period begins and how amendments to the submission are included in the review (proposed

section 703.7).

- The proposed and alternative possible approaches to efficiently developing an acceptable generic name for purposes of listing on the TSCA Inventory, as described in proposed sections 720.102 and 725.190.

- On how to incorporate whether a substance may be readily reverse engineered into the Agency's substantive review criteria in proposed section 703.7(f).

IV. References

The following is a list of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER**

INFORMATION CONTACT.

1. U.S. EPA. Electronic Reporting under the Toxic Substances Control Act; Final Rule. *Federal Register*. 78 FR 72818, December 4, 2013 (FRL-9394-6).

2. U.S. EPA. Economic Impact Analysis for the Procedures for Submitting Information Subject to Business Confidentiality Claims under the Toxic Substances Control Act (TSCA); Proposed Rule. April 4, 2022.

3. U.S. EPA. Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory; Final Rule. *Federal Register*. 85 FR 13062, March 6, 2020 (FRL-10005-48).

4. U.S. EPA. TSCA Chemical Substances; Unique Identifier Assignment and Application Policy; Notice of Availability. *Federal Register*. 83 FR 30168, June 27, 2018 (FRL-9979-59).

5. U.S. EPA. Guidance on Expanded Access to TSCA Confidential Business Information; Notice of Availability. *Federal Register*. 83 FR 30171, June 27, 2018 (FRL-9979-75).

6. U.S. EPA. Statutory Requirements for Substantiation of Confidential Business

Information (CBI) Claims Under the Toxic Substances Control Act (TSCA); Notice. *Federal Register*. 82 FR 6522, January 19, 2017 (FRL-9958-34).

7. U.S. EPA. TSCA Chemical Data Reporting Revisions Under TSCA Section 8(a); Final Rule. *Federal Register*. 85 FR 20122, April 9, 2020 (FRL-10005-56).

8. U.S. EPA. Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting Under the Toxic Substances Control Act; Notice of Availability. *Federal Register*. 83 FR 30173, June 27, 2018 (FRL-9979-02).

9. U.S. EPA. Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under TSCA. Publication ID No. EPA 743B18001. June 2018. Available at: https://www.epa.gov/sites/production/files/2018-06/documents/san6814_guidance_for_creating_tsca_generic_names_2018-06-13_final.pdf.

10. U.S. EPA, Office of Pollution Prevention and Toxics. Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms. June 2, 1997. Available at: https://www.epa.gov/sites/production/files/2015-08/documents/biotech_points_to_consider.pdf.

11. U.S. EPA. Response to Public Comments, TSCA Chemical Data Reporting Revisions for Reporting and Recordkeeping Requirements under TSCA Section 8(a) (RIN 2070-AK33). Document ID No. EPA-HQ-OPPT-2018-0321-0140. March 2020. Available at: <https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0321-0140>.

12. U.S. EPA. Information Collection Request (ICR) entitled: Confidential Business Information Claims under the Toxic Substances Control Act (TSCA) – Proposed Rule (RIN 2070-AK68). EPA ICR No.: 2706.01; OMB Control No.: 2070-NEW. April 4, 2022.

V. Statutory and Executive Orders Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563:

Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). EPA prepared an analysis of the estimated costs and benefits associated with this action (Ref. 2), which is available in the docket and is summarized in Unit I.D. Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of Executive Order 12866.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 2706.01 (Ref. 12). You can find a copy of the ICR in the docket for this action, and it is briefly summarized here.

The reporting requirements identified in this proposed rule implement statutory requirements in TSCA section 14, including new requirements that persons submitting information under TSCA must substantiate most confidentiality claims at the time of submission, as well as additional certification and generic name requirements. In order to maintain most claims beyond a 10-year period, submitters will also be required to reassert and substantiate those claims. Several new requirements also apply to EPA, including requirements to review and approve or deny all chemical identity claims asserted concerning substances that are offered for commercial distribution, as well a subset of all other confidentiality claims, within 90 days of the claim being asserted. Further requirements that EPA review all confidentiality claims concerning substances listed as active on the TSCA Inventory, a requirement to assign and apply unique identifiers (UIDs) to substances with approved confidentiality claims for chemical identity, as well as new provisions providing expanded access to TSCA Confidential Business Information (CBI), have been discussed in previous *Federal Register* documents. Additionally, TSCA rules

promulgated since the Lautenberg amendments have included confidentiality provisions conforming to the amendments (e.g., 40 CFR parts 710 and 711).

Respondents/affected entities: Firms asserting claims for confidentiality in submissions to EPA under TSCA.

Respondent's obligation to respond: Required to obtain or retain a benefit. TSCA section 14; 15 USC 2613.

Estimated number of respondents: 1,100 firms with an estimated additional 55 new firms each year.

Frequency of response: On occasion.

Total estimated burden: 2,945 hours paperwork burden in the first year and 523 hours in each following year. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$ 270,783 in the first year and \$ 44,605 in each following year (2020\$), and an estimated cost of \$ 0 for non-burden hour paperwork costs, e.g., capital investment or maintenance and operational costs.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the *Federal Register*, are listed in 40 CFR part 9, and displayed on the information collection instruments (e.g., forms, instructions).

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at <https://www.reginfo.gov/public/do/PRAMain>. Find this particular ICR by selecting "Currently under Review - Open for Public Comments" or by using the search function. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt,

OMB must receive comments no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The EPA will respond to ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of this action are chemical manufacturers (including importers). EPA estimates that 1,096 small firms would be affected by the proposed requirements. Of those small firms, 100% would have cost impacts of less than 1% of annual revenues, which EPA has determined does not qualify as a significant impact. Details of this analysis are presented in the Economic Analysis of the proposed rule (Ref. 2), which is available in the docket.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 4, 1999). It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It does not have substantial direct effects on tribal government because asbestos is not manufactured (including imported) or processed by tribes and would not impose substantial direct compliance costs on tribal governments.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a “significant energy action” under Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not otherwise been designated by the Administrator of OMB's Office of Information and Regulatory Affairs as a “significant energy action.” The action is predicted to reduce energy use and is not expected to reduce energy supply or increase energy prices.

I. National Technology Transfer and Advancement Act (NTTAA)

This proposed action does not involve any technical standards as specified in NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

List of Subjects

40 CFR Part 2

Administrative practice and procedure, Confidential business information, Courts,

Environmental protection, Freedom of information, Government employees.

40 CFR Part 702

Administrative practice and procedure, Chemicals, Environmental protection, Hazardous substances.

40 CFR Part 703

Administrative practice and procedure, Chemicals, Confidential business information, Environmental protection, Exports, Hazardous substances, Imports, Reporting and recordkeeping requirements.

40 CFR Part 704

Chemicals, Environmental protection, Exports, Hazardous substances, Imports, Reporting and recordkeeping requirements.

40 CFR Part 707

Chemicals, Environmental protection, Exports, Hazardous substances, Imports, Reporting and recordkeeping requirements.

40 CFR Part 716

Chemicals, Confidential business information, Environmental protection, Hazardous substances, Health, Reporting and recordkeeping requirements, Safety.

40 CFR Part 717

Chemicals, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements.

40 CFR Part 720

Chemicals, Environmental protection, Hazardous substances, Imports, Reporting and recordkeeping requirements.

40 CFR Part 723

Chemicals, Environmental protection, Hazardous substances, Phosphate, Reporting and recordkeeping requirements.

40 CFR Part 725

Administrative practice and procedure, Biologics, Chemicals, Environmental protection, Hazardous substances, Imports, Labeling, Microorganisms, Occupational safety and health, Reporting and recordkeeping requirements.

40 CFR Part 790

Administrative practice and procedure, Biologics, Chemicals, Environmental protection, Hazardous substances, Imports, Labeling, Microorganisms, Occupational safety and health, Reporting and recordkeeping requirements.

Authority: 15 U.S.C. 2603, 2604, 2605, 2607, 2613, 2619, and 2625 *et seq.*

Michael S. Regan,

Administrator.

Therefore, for the reasons stated in the preamble, it is proposed that 40 CFR chapter I be amended as follows:

PART 2 – PUBLIC INFORMATION

1. The authority citation for part 2 continues to read as follows:

Authority: 5 U.S.C. 552, 552a, 553; 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717.

2. Revise § 2.306 to read as follows:

§ 2.306 Special rules governing certain information obtained under the Toxic Substances Control Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

(2) *Chemical substance* has the meaning given it in section 3(2) of the Act, 15 U.S.C. 2602(2).

(3) *EPA Legal Office* means the EPA Office of General Counsel and any EPA office over which the EPA General Counsel exercises supervisory authority.

(4) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA

under the Act or under regulations which implement the Act, except for determinations under this subpart.

(b) *Applicability.* This section applies as set forth in 40 CFR 703.1.

(c) *Basic rules that apply without change.* Sections 2.210, 2.211, 2.212, 2.214, and 2.215 apply without change to information to which this section applies. Unless otherwise specified in § 2.306, the provisions in §§ 2.201 through 2.205 and 2.208 do not apply to information subject to this section. Instead, the provisions of 40 CFR part 703 provide the requirements and procedures relevant to confidentiality determinations for information submitted to EPA under the Act.

(d) *Disclosure in special circumstances.* Disclosures of information claimed as confidential under TSCA section 14(d)(4), (5), and (6) may be made in accordance with the provisions of the Act, § 2.306 and any applicable EPA guidance required by section 14(c)(4)(B) of the Act. Section 2.209 applies to information to which this section applies, except that:

(1) The following two additional provisions apply to § 2.209(c):

(i) The official purpose for which the information is needed must be in connection with the agency's duties under any law for protection of health or the environment or for specific law enforcement purposes; and

(ii) EPA notifies the other agency that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the officers and employees of the other agency to the penalties in section 14(h) of the Act (15 U.S.C. 2613(h)).

(2) The 10 business day period for notification specified in § 2.209(b)(2) is instead 15 business days.

(3) The timeline for notification in § 2.209(d) is replaced by the timeline for notification in 15 U.S.C. 2613(g)(2)(B).

(e) *Disclosure of information relevant in a proceeding.* (1) Under section 14(d)(7) of the Act (15 U.S.C. 2613(d)(7)), any information to which this section applies may be disclosed by

EPA when the information is relevant in a proceeding under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. However, any such disclosure shall be made in a manner that preserves the confidentiality of the information to the extent practicable without impairing the proceeding. Disclosure of information to which this section applies because of its relevance in a proceeding shall be made only in accordance with this paragraph (e).

(2) The provisions of § 2.301(g)(2) through (4) apply to disclosures under this paragraph (e).

(f) *Disclosure of information to contractors and subcontractors.* (1) Under section 14(d)(2) of the Act (15 U.S.C. 2613(d)(2)), any information to which this section applies may be disclosed by EPA to a contractor or subcontractor of the United States that is necessary for the satisfactory performance of their work in connection with the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Subject to the limitations in this paragraph (f), information to which this section applies may be disclosed:

(i) To a contractor or subcontractor with EPA, if the EPA program office managing the contract first determines in writing that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract; or

(ii) To a contractor or subcontractor with an agency other than EPA, if the EPA program office which provides the information to that agency, contractor, or subcontractor first determines in writing, in consultation with the General Counsel, that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract.

(2) The provisions of § 2.301(h)(2)(ii) through (iv) apply to disclosures under this paragraph (f).

(3) At the time any information is furnished to a contractor or subcontractor under this paragraph (f), the EPA office furnishing the information to the contractor or subcontractor shall

notify the contractor or subcontractor that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the contractor or subcontractor and its employees to the penalties in section 14(d) of the Act (15 U.S.C. 2613(d)).

(g) Disclosure of information when necessary to protect health or the environment against an unreasonable risk of injury. (1) Under section 14(d)(3) of the Act (15 U.S.C. 2613(d)(3)), any information to which this section applies may be disclosed by EPA when disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment, without consideration of costs, or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation as relevant by EPA under conditions of use. However, any disclosure shall be made in a manner that preserves the confidentiality of the information to the extent not inconsistent with protecting health or the environment against the unreasonable risk of injury. Disclosure of information to which this section applies because of the need to protect health or the environment against an unreasonable risk of injury shall be made only in accordance with this paragraph (g).

(2) If any EPA office determines that there is an unreasonable risk of injury to health or the environment and that to protect health or the environment against the unreasonable risk of injury it is necessary to disclose information to which this section applies that otherwise might be entitled to confidential treatment under this subpart, the EPA office shall notify the EPA Legal Office in writing of the nature of the unreasonable risk of injury, the extent of the disclosure proposed, how the proposed disclosure will serve to protect health or the environment against the unreasonable risk of injury, and the proposed date of disclosure. Such notification shall be made as soon as practicable after discovery of the unreasonable risk of injury. If the EPA office determines that the risk of injury is so imminent that it is impracticable to furnish written notification to the EPA Legal Office, the EPA office shall notify the EPA Legal Office orally.

(3) Upon receipt of notification under paragraph (g)(2) of this section, the EPA Legal Office shall make a determination in writing whether disclosure of information to which this

section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury. The EPA Legal Office shall also determine the extent of disclosure necessary to protect against the unreasonable risk of injury as well as when the disclosure must be made to protect against the unreasonable risk of injury.

(4) If the EPA Legal Office determines that disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury, the EPA Legal Office shall furnish notice to each affected business of the contemplated disclosure and of the Legal Office's determination. Such notice shall be made in writing, via either electronic notice as described in 40 CFR 703.5(h) or by certified mail, return receipt requested, at least 15 business days before the disclosure is to be made. The notice shall state the date upon which disclosure will be made. However, if the EPA Legal Office determines that disclosure of the information is necessary to protect against an imminent and substantial harm to health or the environment, no prior notification is necessary.

PART 702 – GENERAL PRACTICES AND PROCEDURES

3. The authority citation for part 702 continues to read as follows:

Authority: 15 U.S.C. 2605 and 2619.

4. Revise § 702.37(d) to read as follows:

§ 702.37 Submission of manufacturer requests for risk evaluations.

* * * * *

(d) *Confidential business information.* Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

* * * * *

5. Add part 703 to read as follows:

PART 703 – CONFIDENTIALITY CLAIMS

Sec.

703.1 Purpose and applicability.

703.3 Definitions.

703.5 Requirements for asserting and maintaining confidentiality claims.

703.7 EPA review of confidentiality claims under TSCA Section 14(g).

703.8 EPA review of confidentiality claims under TSCA Section 14(f).

Authority: 15 U.S.C 2613.

§ 703.1 Purpose and applicability.

(a) The purpose of this part is to describe procedures for asserting and maintaining confidentiality claims in accordance with TSCA section 14, and for EPA review of such claims. The procedures described in this part are generally applicable to the submission and EPA review of any TSCA submission, except to the extent that application of the requirements would be inconsistent with TSCA section 14(i). The procedures include requirements concerning the form and manner in which TSCA submissions must be made to meet the requirements in TSCA section 14(b) and (c), to facilitate EPA review of such claims in accordance with TSCA section 14(f) and (g), and to facilitate disclosure of non-confidential information to the public in accordance with TSCA, FOIA, and their implementing regulations.

(b) This part applies to all information that is reported to or otherwise obtained by EPA pursuant to TSCA or its implementing regulations. Unless otherwise specified in 40 CFR 2.306, the provisions of 40 CFR 2.201 through 2.205 and 40 CFR 2.208 do not apply to information subject to this part. This part also applies to information that satisfies all three of the following criteria:

(1) The information was first obtained by EPA other than pursuant to the authority of TSCA or its implementing regulations;

(2) EPA has authority to collect the information under TSCA; and

(3) Either:

(i) Subsequent to its submission the information is being used to satisfy the obligation of a person under TSCA or its implementing regulations; or

(ii) EPA makes use of the information in the course of carrying out its responsibilities under TSCA.

(c)(1) This part applies regardless of:

(i) Whether the information is intended by its submitter to be used by EPA in implementing TSCA;

(ii) Whether TSCA or an implementing regulation was cited as authority for the request or submission of the information; or

(iii) Whether the information was provided directly to EPA or through some third person.

(2) In the event the information satisfies the requirements of § 703.1, and such information was originally submitted to or obtained by EPA under another statute, and the other statute or its implementing regulations prescribe conflicting rules for the treatment of the information, the statute or rule under which the information was provided to EPA shall govern, except that the provisions in 40 CFR 2.306(d) through (f) apply, where relevant, to how EPA may share such information.

§ 703.3 Definitions.

The definitions in this section and the definitions in TSCA section 3 apply to this part. In addition, the definition in § 720.3(ff) for *test data* also applies in this part.

Accepted in the context of asserting a TSCA CBI claim means the date that EPA first approved the submission in CISS, or its successor system.

CDX or Central Data Exchange means EPA's centralized electronic document receiving system, or its successor system.

CISS or Chemical Information Submission System means EPA's web-based reporting tool for preparing and submitting TSCA submissions, or its successor system.

Confidentiality claim means a claim or allegation that business information is entitled to confidential treatment.

Health and safety study has the same meaning as that provided in § 720.3(k), except that for purposes of this part 703 the following information is not part of a health and safety study:

- (1) The name of the submitting company;
- (2) The name of the laboratory conducting the study;
- (3) Internal product codes;
- (4) The names of laboratory personnel;
- (5) Names of individual study subjects and other private information included in study data or reports;
- (6) Cost and other financial data; and
- (7) Product development, advertising, and marketing plans.

§ 703.5 Requirements for asserting and maintaining confidentiality claims.

Any person who submits information under TSCA or these implementing regulations may assert a business confidentiality claim to information included in such submission. Such claim must be made concurrent with submission of the information. If no such claim accompanies the submission, EPA will not recognize a confidentiality claim, and the information in or referred to in that submission may be made available to the public (e.g., by publication of specific chemical name and CASRN on the public portion of the TSCA Inventory) without further notice.

(a) *Supporting statement and certification.* A person asserting a confidentiality claim must submit a statement that the person has:

- (1) Taken reasonable measures to protect the confidentiality of the information;
- (2) Determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (3) A reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and
- (4) A reasonable basis to believe that the information is not readily discoverable through

reverse engineering.

(5) The person must also certify that these four statements and any information required to substantiate the confidentiality claim in accordance with paragraph (b) of this section are true and correct.

(b) *Substantiation.* (1) *Timing of substantiation.* Confidentiality claims must be substantiated at the time of submission to EPA, unless exempt under paragraph (b)(5) of this section. In the case of information collected by EPA or on behalf of EPA in person at the site of a TSCA inspection under section 11 of the Act, the affected company must assert its confidentiality claim(s) in writing at the time the information is collected, and then must provide substantiation of its confidentiality claims and the supporting statement and certification described in paragraph (a) of this section within ten working days after the inspection ends.

(2) *Confidentiality claims in substantiation.* Information in substantiations may be claimed as confidential. Such claims must be accompanied by the certification described in paragraph (a) of this section, but need not be themselves substantiated.

(3) *Substantiation questions for all claims.* Unless otherwise specified elsewhere in 40 CFR 700 *et seq* (e.g., 40 CFR part 711), answers to the following questions must be provided for each confidentiality claim in a TSCA submission:

(i) Please specifically explain what harm to the competitive position of your business would be likely to result from the release of the information claimed as confidential. How would that harm be *substantial*? Why is the substantial harm to your competitive position *likely* (i.e., probable) to be caused by release of the information rather than just *possible*? If you claimed multiple types of information to be confidential (e.g., site information, exposure information, environmental release information, etc.), explain how disclosure of each type of information would be likely to cause substantial harm to the competitive position of your business.

(ii) Has your business taken precautions to protect the confidentiality of the disclosed information? If yes, please explain and identify the specific measures, including but not limited

to internal controls, that your business has taken to protect the information claimed as confidential. If the same or similar information was previously reported to EPA as non-confidential (such as in an earlier version of this submission), please explain the circumstances of that prior submission and reasons for believing the information is nonetheless still confidential.

(iii)(A) Is any of the information claimed as confidential required to be publicly disclosed under any other Federal law? If yes, please explain.

(B) Does any of the information claimed as confidential otherwise appear in any public documents, including (but not limited to) safety data sheets; advertising or promotional material; professional or trade publications; state, local, or Federal agency files; or any other media or publications available to the general public? If yes, please explain why the information should be treated as confidential.

(C) Does any of the information claimed as confidential appear in one or more patents or patent applications? If yes, please provide the associated patent number or patent application number (or numbers) and explain why the information should be treated as confidential.

(iv) Is the claim of confidentiality intended to last less than 10 years (see TSCA section 14(e)(1)(B))? If yes, please indicate the number of years (between 1 and 10 years) or the specific date after which the claim is withdrawn.

(v) Has EPA, another Federal agency, or court made any confidentiality determination regarding information associated with this chemical substance? If yes, please provide the circumstances associated with the prior determination, whether the information was found to be entitled to confidential treatment, the entity that made the decision, and the date of the determination.

(4) *Additional substantiation questions for chemical identity-related claims only.* Unless otherwise specified in the relevant electronic reporting form, answers to the following questions must be provided for each chemical identity-related confidentiality claim in a TSCA submission:

(i) Is this chemical substance publicly known (including by your competitors) to be in U.S. commerce? If yes, please explain why the specific chemical identity should still be afforded confidential status (e.g., the chemical substance is publicly known only as being distributed in commerce for research and development purposes, but no other information about the current commercial distribution of the chemical substance in the United States is publicly available). If no, please complete the certification statement:

I certify that on the date referenced I searched the internet for the chemical substance identity (*i.e.*, by both chemical substance name and CASRN). I did not find a reference to this chemical substance and have no knowledge of public information that would indicate that the chemical is being manufactured or imported by anyone for a commercial purpose in the United States. [provide date].

(ii) Does this specific chemical substance leave the site of manufacture (including import) in any form, e.g., as a product, effluent, emission? If yes, please explain what measures have been taken to guard against the discovery of its identity.

(iii) If the chemical substance leaves the site in a form that is available to the public or your competitors, can the chemical identity be readily discovered by analysis of the substance (e.g., product, effluent, emission), in light of existing technologies and any costs, difficulties, or limitations associated with such technologies? Please explain why or why not.

(iv) Would disclosure of the specific chemical identity release confidential process information? If yes, please explain.

(5) *Exemptions from the substantiation requirement.* Information described in paragraphs (b)(5)(i) and (b)(5)(ii) of this section is exempt from the requirement to substantiate the claim at the time of submission. EPA may identify on a reporting form certain information as exempt from substantiation. Additional assertions of exemption from substantiation may be asserted by the submitter. Each such assertion must include a detailed explanation for why the information falls within the claimed exemption. If the explanation is missing or inadequate, and the claim is not otherwise substantiated, EPA will place a hold on the submission, as described in paragraph (d) of this section.

(i) The following information types are exempt from the substantiation requirement at the time of information submission:

(A) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article;

(B) Marketing and sales information;

(C) Information identifying a supplier or customer;

(D) Details of the full composition of a mixture and the respective percentages of constituents;

(E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article; and

(F) Specific production or import volumes.

(ii) Exemption for chemical substances not yet offered for commercial distribution.

(A) A confidentiality claim for specific identity of a chemical substance, where the submission is made prior to the date on which the chemical substance whose identity is claimed as confidential is first offered for commercial distribution, is exempt from the requirement to substantiate confidentiality claims at the time of submission.

(B) A specific chemical identity claim includes specific chemical names, CAS numbers, molecular formulas, reactants (if required to be reported as part of the identification of the chemical, such as for Class 2 substances in § 720.45(a)), and structural diagrams; or in the case of microorganisms, genus and species name and genetic construct.

(C) This exemption applies where the submitter lacks information to reasonably conclude that the chemical substance has been offered for commercial distribution, where both:

(1) The chemical substance is not on the TSCA Inventory, and

(2) The substance is otherwise not publicly known to have been offered for commercial distribution.

(c) *Public copies.* All TSCA submissions and their accompanying attachments that

include a confidentiality claim must be accompanied, at the time of submission, by a public version of the submission and any attachments, with all information that is claimed as confidential removed. In the case of documents collected by EPA or on behalf of EPA in person at the site of a TSCA inspection under section 11 of the Act, the affected company must provide such public copies at the same time as it provides substantiation of its confidentiality claims in accordance with paragraph (b)(1) of this section, within ten working days after the inspection ends. Only information that is claimed as confidential may be redacted or removed. Generally, a public copy that removes all or substantially all of the information would not meet the requirements of this paragraph (c) of this section and the submission may be temporarily put on hold as deficient.

(1) Where the applicable reporting form or electronic reporting tool contains a checkbox or other means of designating with specificity what information is claimed as confidential, no further action by the submitter is required to satisfy this requirement.

(2) For all other information claimed as confidential, including but not limited to information in attachments and in substantiations required under paragraph (b) of this section, the submitter must prepare and attach a public copy. EPA may hold as deficient submissions with public or sanitized copies that are entirely blank or that are substantially reduced in length as compared to the CBI version (see paragraph (e) of this section).

(d) *Generic name.* Each confidentiality claim for specific chemical identity must be accompanied by a structurally descriptive generic name for that substance. This generic name must be consistent with guidance on the determination of structurally descriptive generic names developed in accordance with TSCA section 14(c)(4)(A) (e.g., *Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under TSCA*; available at <https://www.epa.gov/tsca-inventory/guidance-creating-generic-names-confidential-chemical-substance-identity-reporting>), and 15 U.S.C. 2613(c)(1)(C)(ii).

(1) At a minimum, the generic name must either:

(i) Be identical to the generic name for the same substance included on the non-confidential portion of the TSCA Inventory (if the substance is listed on the TSCA Inventory), or

(ii) For substances that are not listed on the TSCA Inventory, mask only the confidential portions of the specific chemical name. In most cases, only one structural element of a specific chemical name may be masked to protect a confidential chemical identity—if the submitter of a proposed generic name wishes to mask more than one such element, the submission must include an explanation of why masking only one element is insufficient to protect the confidential identity.

(2) Notwithstanding paragraph (d)(1) of this section, EPA may conclude that a generic name provided with the submission and listed on the current non-confidential version of the TSCA Inventory does not comply with 15 U.S.C. 2613(c)(1)(C). In such cases, EPA will notify the submitting company and proceed as described in paragraph (c)(4) of this section.

(3) A generic name that meets the requirements of section 14(c)(1)(C) of the Act prior to the date on which the chemical substance is first offered for commercial distribution for the purposes of a pre-market submission (e.g., a PMN) may not be sufficient for the purposes of subsequent listing on the TSCA Inventory, as identified upon review under section 14(g)(1)(C)(i) of the Act of a confidentiality claim for specific chemical identity made in a Notice of Commencement required under § 720.102 or § 725.190(f). In such cases, EPA will notify the submitting company and proceed as described in § 720.102(f) or § 725.190(f).

(4) If EPA concludes that the proposed generic name does not comply with 15 U.S.C. 2613(c)(1)(C), EPA will notify the submitter, and provide 10 business days for the submitter to provide a revised generic name. If EPA concludes that the revised generic name is still not acceptable, EPA will hold the submission for an additional period of up to 10 business days, and proceed as set out in paragraph (e) of this section.

(e) *Deficient confidentiality claims.* (1) A confidentiality claim under TSCA is deficient if it meets one or more of the following criteria:

(i) The confidentiality claim is not accompanied by the supporting statement and certification required by paragraph (a) of this section.

(ii) The confidentiality claim is not accompanied by the substantiation required by paragraph (b) of this section. If the submitter claims an exemption from substantiation under paragraph (b)(5) of this section and the exemption does not apply or an explanation is not provided for the exemption pursuant to paragraph (b)(5) of this section, the confidentiality claim is deficient.

(iii) The confidentiality claim is not accompanied by a public copy that meets the requirements of paragraph (c) of this section.

(iv) The confidentiality claim is for a specific chemical identity and is not accompanied by a generic name that meets the requirements of paragraph (d) of this section.

(2) A submission that is identified as deficient under paragraph (e)(1) of this section will be held for a period of up to 10 business days, and the submitter will be notified via CDX as described in paragraph (h) of this section. During the hold, which commences on the day the CDX notice is sent, any applicable review period for the underlying submission will be suspended until either the deficiency is corrected or the 10 business days elapse without such correction. Upon the occurrence of the first of either of these events, the applicable review period for the underlying submission commences or comes out of suspension. If the deficiency is not remedied during the suspension, EPA will proceed with review of the submission and may deny the CBI claim(s).

(f) *Electronic reporting required.* (1) Except in the case of information subpoenaed under TSCA section 11(c) or materials collected or requested by EPA as part of an inspection under TSCA section 11(a), TSCA submissions bearing confidentiality claims must be submitted via CDX.

(2) You must use CISS to complete and submit TSCA submissions via CDX. To access CISS go to <https://cdx.epa.gov/> and follow the appropriate links.

(3) On receipt by EPA, each electronic TSCA submission will be assigned a case number or document identifier, which will be available to the submitter in their CDX account. This identifier may be used as a reference in future communications that concern the substance, and may be used by EPA in public communications (e.g., *Federal Register* notices) that concern the submission, such as notices of receipt, final confidentiality determination, pending confidentiality claim expiration, or in other regulatory actions that concern the TSCA submission.

(g) *Requirement to report health and safety studies using templates.* Submitters of health and safety studies or information from such studies must provide such data in templated form, using an appropriate OECD harmonized template, if such template is available for the data type (<https://www.oecd.org/ehs/templates/>). Individual test or data submission rules or orders may specify an appropriate template or templates. Submission of templated data is not a substitute for submitting a full study report where a specific TSCA rule or order requires submission of the full study report (e.g., § 720.50(a), or according to the terms of a specific order under TSCA section 5(e)).

(h) *Requirement to maintain company contact information; electronic notices concerning confidentiality claims.* (1) To facilitate ongoing or future communication concerning TSCA submissions, current contact information for all of the individuals associated with a particular TSCA submission must be maintained. Contact information for all the individuals associated with a particular TSCA submission must be updated by amending the submission via CDX, except that submissions that are either no longer accessible to the submitting company or that were not submitted via CDX (e.g., submissions that were originally provided on paper or other physical media), updated company contact must be provided via CDX using the appropriate EPA-provided electronic reporting application in CISS. In circumstances where ownership of the company or unit of a company has changed, such that contact information for one or more prior TSCA submissions that include confidentiality claims is affected, a notice of transfer of

ownership must be directed to EPA via CDX. Instructions for providing this notice and for requesting access to copies of a prior TSCA submission are available at <https://cdx.epa.gov/>.

(2) When EPA contacts a TSCA submitter concerning confidentiality claims (e.g., related to a pending or concluded confidentiality claim review, a deficient submission, or in relation to the 10-year expiration of a confidentiality claim (described in TSCA section 14(e)), EPA may provide notices and other correspondence to the submitter via CDX, using the contact information provided in the most recent version of the submission, or using the contact information provided in a more recent notice of transfer of ownership relating to that submission. The fact and date of delivery of such notice is verified automatically by CDX.

(3) In addition to individual notice described in paragraph (h)(2) of this section, EPA will publish on its website, or other appropriate platform, a list of TSCA submissions with confidentiality claims that are approaching the end of the ten-year period of protection described in TSCA section 14(e). Such TSCA submissions will be referred to by the TSCA case or document identifier (as described in paragraph (f)(3) of this section) that was assigned to the submission by EPA when it was originally submitted. TSCA submissions will be added to this list at least 60 days prior to the end of the ten-year period of protection, along with instructions for reasserting and substantiating expiring claims.

(4) When a confidentiality claim is being reviewed pursuant to TSCA section 14(f), EPA will provide, when necessary, notice of such review and an opportunity to substantiate or resubstantiate the affected confidentiality claim to the submitter using the contact information for the authorized official or technical contact provided in the most recent version of the submission or in a more recent notice of transfer of ownership relating to that submission.

(5) Where the submission with the relevant CBI claim was not originally made via CDX, EPA will send the notice via courier or US Mail to the company address provided in the most recent TSCA submission made by that company, or via other means that allows verification of the fact and date of receipt. The notice will provide instructions for substantiating claims that

were exempt from substantiation when the confidentiality claim was asserted or for which the submitter was otherwise not required to provide substantiation at the time of initial submission, and for updating or re-substantiating as necessary any claims that were previously substantiated.

(i) *Withdrawing confidentiality claims.* TSCA confidentiality claims may be voluntarily withdrawn by the submitter at any time.

(1) Confidentiality claims in TSCA submissions that were originally made via electronic submission may be withdrawn by reopening the submission in CDX, removing confidentiality markings (e.g., confidential checkmarks or bracketing), revising sanitized attachments or copies as appropriate, and then resubmitting the submission.

(2) For submissions that were not originally made via CDX, or that are no longer accessible to the submitting company via CDX, confidentiality claims may also be withdrawn via CDX using the “TSCA Communications” application or successor system. The withdrawal correspondence must indicate the case or document number (or other applicable document identifier or document identifying details) from which CBI claims are being withdrawn, identify the submitting company, and include a list or description of the information for which CBI claims are being withdrawn, including page numbers where relevant. Current contact information for the person withdrawing the claim must also be provided, in the event EPA needs clarification concerning which claim or claims are being withdrawn.

(j) *Amending public copy following confidentiality claim denial or expiration.* (1) Following the expiration or EPA’s denial of a TSCA confidentiality claim, the person who asserted the denied or expired claim should prepare and submit a revised public copy of the submission to EPA, following the procedures for voluntarily withdrawing claims described in § 703.5(i).

(2) If the person who asserted the denied or expired claim declines or fails to provide within 30 days a revised public copy of the submission that includes the information for which

the confidentiality claim(s) were denied or expired, EPA may prepare an addendum to the original public copy, as needed, in order to provide the newly available information to the public.

§ 703.7 EPA review of confidentiality claims under TSCA Section 14(g)

(a) *Representative subset.* (1) *Definition.* A *representative subset* consists of at least 25% of confidentiality claims asserted under TSCA, not including claims for specific chemical identity or for the categories of information listed in section 14(c)(2) of TSCA. Excluded from the representative subset are

(i) Inquiries with respect to potential submission to EPA of a notification under 40 CFR part 720, 721, 723 or 725 by a person who has not submitted the notification at the time of the inquiry, including inquiries under § 720.25(b) or 721.11;

(ii) Submissions or other communication not submitted to EPA via CDX; and

(iii) Amendments to previous TSCA submissions.

(2) *Selection of submissions for review.* To satisfy its confidentiality claim review obligations under section 14(g)(1)(C)(ii) of TSCA, EPA may review all claims (except those exempt from substantiation under TSCA section 14(c)(2)) in every fourth TSCA submission submitted via CDX that is part of the representative subset, in chronological order of receipt by EPA. For each submission selected for review as part of the representative subset, EPA reviews and approves or denies every individual confidentiality claim in that submission (except claims that are exempt under TSCA sections 14(c)(2) and 14(g)), including claims made in attachments and amendments available to EPA at the time of the review.

(b) *Review of new and expiring confidentiality claims under TSCA Section 14(g).* (1) Under TSCA Section 14(g), EPA will **review:**

(i) All chemical identity claims asserted in TSCA submissions except those that are exempt from substantiation according to TSCA Section 14(c)(2)(G), and

(ii) A representative subset of other confidentiality claims as provided in paragraph (a) of this section.

(2) EPA will review all timely requests for extension of claims under section 14(e) of TSCA within 30 days of receipt.

(3) EPA will also review or re-review confidentiality claims under certain other circumstances, as set out in TSCA section 14(f). TSCA section 14(f) reviews are conducted in accordance with procedures set out in § 703.8.

(c) *Commencement of the review period and effect of amendments.* Subject to § 703.5(e), the 90-day review period described in TSCA section 14(g) begins on the day that EPA accepts a new TSCA submission that includes confidentiality claims. For new information, other than specific chemical identity, added to a submission after EPA first accepts the submission, the review will take into account such amendments to that submission that are made either up to 60 days from the original submission date, or until the Agency issues a final confidentiality determination for the submission, whichever comes first. If a submission is amended to report an additional or different chemical substance that includes a new specific chemical identity claim, the TSCA section 14(g) review period for the added chemical identity begins on the day EPA accepts the amendment including the new claim.

(d) *Publication of final determinations.* Final confidentiality determinations will be published on EPA's website, or other platform, periodically, in accordance with the requirements of TSCA section 26(j).

(e) *Claim denials and notice period.* Final determinations will be issued by the General Counsel or their designee, which may include personnel outside of the Office of General Counsel. In the case that EPA determines that a claim or part of a claim is not entitled to confidential treatment, EPA will provide notice of the denial to the person who made the claim and provide reasons for the denial or denial in part. The notice will be provided electronically, as described in § 703.5(h)(2). The 30-day notice period described in TSCA section 14(g)(2)(B) begins on the next business day following the date the notice is made available to the submitter in their CDX account.

(f) *Substantive criteria for use in confidentiality determinations.* Information claimed as confidential under TSCA section 14 will be approved if:

(1) The business has asserted a business confidentiality claim which has not expired by its terms, nor been waived nor withdrawn;

(2) The business has satisfactorily shown that it has taken reasonable measures to protect the confidentiality of the information, and that it intends to continue to take such measures for as long as the claim is maintained;

(3) The information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding; e.g., the business has demonstrated a reasonable basis to believe the information is not readily discoverable through reverse engineering);

(4) The business has demonstrated a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the business; and

(5) No statute denies confidential protection to the information. Information from health and safety studies is not entitled to confidential treatment, except that the following information may be entitled to confidential treatment if it otherwise meets the remainder of criteria in this paragraph (f):

(i) Any information, including formulas (including molecular structures) of a chemical substance or mixture, that discloses processes used in the manufacturing or processing of a chemical substance or mixture; or

(ii) In the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.

(g) *Request for Reconsideration.* Persons who received a denial or partial denial notification under paragraph (e) of this section may request reconsideration by the Office of General Counsel prior to the end of the 30-day period specified in the notice and described

under paragraph (e) of this section. The business must make its request for reconsideration electronically via CDX, following the instructions in the notice. If a request for reconsideration is timely received, EPA will suspend the 30-day notice period described in paragraph (e) of this section while the Office of General Counsel reconsiders the Agency's determination. Once the Office of General Counsel's reconsideration is complete, the Agency will provide notification, pursuant to § 703.5(h), to the person of EPA's decision on the request for reconsideration. If upon reconsideration the Agency upholds the confidentiality determination, the 30-day notice period will resume. The Office of General Counsel will perform its review de novo and will only reconsider determinations based on the information included with the original submission and amendments made up until the time the final determination was issued.

(h) *Criteria to use in consideration of requests for extension under TSCA section 14(e).* Requests to extend the period of confidentiality protection under TSCA section 14(e) use the same criteria as described under § 703.7(f). Requests for extension may rely on a substantiation previously provided to EPA, but the submitter must recertify that the substantiation is still true and correct.

§ 703.8 EPA review of confidentiality claims under TSCA section 14(f).

(a) *Review of confidentiality claims initiated under TSCA Section 14(f).* In accordance with the procedures described in this section, EPA may review confidentiality claims that are subject to TSCA section 14(f)(1), and will review confidentiality claims subject to TSCA section 14(f)(2) in the following situations:

- (1) In response to a request under the Freedom of Information Act (5 U.S.C. 552) for TSCA information claimed confidential;
- (2) If EPA has reason to believe that information claimed confidential does not qualify for protection from disclosure; or
- (3) For any chemical substance EPA determines under TSCA section 6(b)(4)(A) presents an unreasonable risk of injury to health or the environment.

(b) *Substantiation exemptions not applicable.* All confidentiality claims asserted in submissions described by paragraph (a) of this section are subject to the substantiation requirements, including those that were initially exempt from substantiation according to section 14(c)(2) of TSCA.

(c) *Additional substantiation.* If necessary, such as in the case that substantiation has not previously been provided for confidentiality claims under review, or in the case that EPA has reason to believe the substantiation is incomplete or out of date, EPA will request additional substantiation from the person(s) that claimed the information as confidential.

(d) *Additional substantiation notice.* If additional substantiation is necessary, EPA will provide notice to the person that claimed the information as confidential in the manner specified in § 703.5(h)(4). The notice will provide the time allowed for additional substantiation from the business and the method for requesting a time extension if necessary. If the person does not make a timely response or extension request, EPA will consider any existing substantiations in its review of the claims or, in the case of any unsubstantiated claim, EPA will construe this as a waiver of the claim and may make the information public without any further notice to the submitter.

(e) *Substantive criteria for use in confidentiality determinations.* The criteria in § 703.7(f) apply to confidentiality determinations initiated under TSCA section 14(f). For determinations required to respond to a FOIA request, the criteria in § 703.7(f) are supplemented with one additional criterion that must be satisfied: The business adequately demonstrates that the information is commercial or financial information obtained from a person and is confidential within the meaning of FOIA Exemption 4 (5 U.S.C. 552(b)(4)).

(f) *Adverse determinations and notice period.* Final determinations will be issued by the General Counsel or their designee, including personnel outside of the Office of General Counsel. Except for instances where claims were waived, if EPA determines that information claimed confidential does not qualify for protection from disclosure, EPA will provide written notice to

the person who asserted the claim. The notice will be provided electronically, as described in § 703.5(h)(2). The 30-day notice period described in TSCA section 14(g)(2)(B) begins on the next business day following the date the notice is made available to the submitter in their CDX account.

(g) *Disclosure of Information.* After a final determination has been made by EPA to release some or all of the information claimed as confidential, the Agency shall make the information available to the public (in the absence of a court order prohibiting disclosure) whenever:

(1) The period provided for commencement by a business of an action to obtain judicial review of the determination has expired without notice to EPA of commencement of such an action; or

(2) The court, in a timely-commenced action, has denied the person's motion for a preliminary injunction, or has otherwise upheld the EPA determination.

(h) *Notice relating to public requests for records.* Any person whose request for release of the information under 5 U.S.C. 552 is pending at the time notice is given under paragraph (f) of this section shall be furnished notice under 5 U.S.C. 552 either stating the circumstances under which the some or all of the information will be released or denying the request if all requested information was found to be entitled to confidential treatment.

PART 704 – REPORTING AND RECORDKEEPING REQUIREMENTS

6. The authority citation for part 704 continues to read as follows:

Authority: 15 U.S.C 2607(a).

7. Revise § 704.7 to read as follows:

§ 704.7 Confidential business information claims.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

PART 707 – CHEMICAL IMPORTS AND EXPORTS

8. The authority citation for part 707 continues to read as follows:

Authority: 15 U.S.C 2611(b) and 2612.

9. Amend § 707.63 by redesignating paragraphs (a) through (d) as paragraphs (b) through (e) and adding a new paragraph (a) to read as follows:

§ 707.63 Definitions.

(a) *CDX or Central Data Exchange* means EPA's centralized electronic document receiving system, or its successor system.

10. Amend § 707.65 by revising paragraphs (a)(1) and (2), removing paragraph (a)(3), and revising paragraph (c) to read as follows:

§ 707.65 Submission to the Agency.

(a) * * *

(1)(i) The notice must be for the first export or intended export by an exporter to a particular country in a calendar year when the chemical substance or mixture is the subject of an order issued, an action that is pending, or relief that has been granted under TSCA section 5(f), a rule that has been proposed or promulgated under TSCA section 6, or an action that is pending or relief that has been granted under TSCA section 7.

(ii) The notice must only be for the first export or intended export by an exporter to a particular country when the chemical substance or mixture is the subject of an order issued, an action that is pending, or relief that has been granted under TSCA section 5(e), a rule that has been proposed or promulgated under TSCA section 5(a)(2), or when the submission of data is required under TSCA section 4 or 5(b). Under this paragraph (a)(1)(ii), notice of export to a particular country is not required if an exporter previously submitted to EPA a notice of export to that country prior to January 16, 2007.

(2) The notice must be submitted to EPA within seven days of forming the intent to export or on the date of export, whichever is earlier. A notice of intent to export must be based on a definite contractual obligation, or an equivalent intra-company agreement, to export the

regulated chemical.

* * * * *

(c) Notices must be submitted via CDX, using the TSCA section 12(b) Export Notification Application or its successor.

11. Amend § 707.67 by revising paragraph (a) to read as follows:

§ 707.67 Contents of notice.

* * * * *

(a) The name of the regulated chemical as it appears in the TSCA section 4, 5, 6, and/or 7 action. For substances on the confidential portion of the TSCA Inventory, this means that the substance must be identified by generic name and accession number, or by any other non-confidential identifier under which it is listed on the TSCA section 12(b) reporting list maintained by EPA and available in the TSCA section 12(b) Export Notification Application described in § 707.65(c). If a category is regulated, the name of the individual regulated chemical within that category, as well as the category, must be given. The name must be that which appears in the TSCA Inventory, if the chemical appears there.

* * * * *

12. Amend § 707.75 by revising paragraph (d) to read as follows:

§ 707.75 Confidentiality

* * * * *

(d) Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

PART 716 HEALTH AND SAFETY DATA REPORTING

12. The authority citation for part 716 continues to read as follows:

Authority: 15 U.S.C 2607(d).

13. Revise § 716.55 to read as follows:

§ 716.55 Confidentiality claims.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

PART 717 RECORDS AND REPORTS OF ALLEGATIONS THAT CHEMICAL SUBSTANCES CAUSE SIGNIFICANT ADVERSE REACTIONS TO HEALTH OR THE ENVIRONMENT

14. The authority citation for part 717 continues to read as follows:

Authority: 15 U.S.C 2607(c).

15. Amend § 717.17 by revising paragraph (c) to read as follows:

§ 717.17 Inspection and reporting requirements.

* * * * *

(c) *How to Report.* When required to report, firms must submit copies of records via CDX <https://cdx.epa.gov/> using the EPA provided electronic reporting application.

16. Revise § 717.19 to read as follows:

§ 717.19 Confidentiality.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

PART 720 – PREMANUFACTURE NOTIFICATION

17. The authority citation for part 720 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2613.

18. Revise § 720.80 to read as follows:

§ 720.80 General provisions.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

* * * * *

§ 720.85 [Removed]

19. Remove § 720.85.

§ 720.90 [Removed]

20. Remove § 720.90.

21. Revise § 720.95 to read as follows:

§ 720.95 Public file.

All information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice, unless such materials are claimed confidential in accordance with procedures in 40 CFR 703.5. In addition, EPA may add materials to the public file, subject to subpart E of this part. Publicly available materials are available at the docket addresses in § 700.17(b)(1) and (2) of this chapter and on EPA's website.

22. Amend § 720.102 by revising paragraph (c)(2) and adding paragraphs (e) and (f) to read as follows:

§ 720.102 Notice of commencement of manufacture or import.

* * * * *

(c) * * *

(2) If the submitter claims any information on the form as confidential, the claim must be asserted and substantiated in accordance with the requirements described in 40 CFR part 703 and must be submitted via EPA Form 7710-56. If the submitter wants the chemical identity to be listed on the confidential portion of the TSCA Inventory, the chemical identity must be claimed as confidential and the submitter must also follow the certification, substantiation, and generic name requirements described part 703 and paragraphs (e) and (f) of this section. Otherwise, EPA will list the specific chemical identity on the public TSCA Inventory. Submitters who did not claim the chemical identity, submitter identity, or other information to be confidential in the PMN cannot claim this information as confidential in the notice of commencement.

* * * * *

(e) *Confidentiality.* (1) Any person who asserts a confidentiality claim for chemical

identity in a Notice of Commencement submitted under § 720.102 must:

(i) Comply with generic name requirements described in part 703 and as specified in paragraph (f) of this section.

(ii) Agree that EPA may disclose to a person with a bona fide intent to manufacture or import the chemical substance the fact that the particular chemical substance is included on the confidential TSCA Inventory for purposes of notification under section 5(a)(1)(A) of the Act.

(iii) Have available for the particular chemical substance, and agree to furnish to EPA upon request:

(A) An elemental analysis.

(B) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the chemical substance.

(2) Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

(f) *Generic Name*. If a submitter asserts a claim of confidentiality for chemical identity in a notice of commencement, they must provide a structurally descriptive generic name.

(1) Generic names must:

(i) Be structurally descriptive (e.g., not a trade name);

(ii) Describe the chemical structure of the chemical substance as specifically as practicable while protecting only those features of the chemical structure that are claimed as confidential and disclosure of which would likely cause substantial harm to the competitive position of the person--the generic name should generally only obscure one structural feature, but in any case, should conceal only the feature(s) necessary to avoid a likelihood of substantial competitive harm to the submitter; and

(iii) Be consistent with guidance on the determination of structurally descriptive generic

names, developed in accordance with TSCA section 14(c)(4)(A) (e.g., *Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under TSCA*; available at <https://www.epa.gov/tsca-inventory/guidance-creating-generic-names-confidential-chemical-substance-identity-reporting>).

(2) Generic names will be reviewed by EPA at the time of submission. (i) If EPA concludes that a proposed generic name meets the criteria in paragraph (f)(1) of this section, EPA will include that generic name in the public TSCA Inventory listing for that substance.

(ii) If the proposed generic name does not meet the criteria in paragraph (f)(1) of this section, EPA will notify the submitter concerning the deficiency via CDX, as described in 40 CFR 703.5(f). EPA will provide 10 business days to correct the deficiency and provide an alternative generic name that would be acceptable to EPA. If the alternative generic name proposed by EPA is acceptable to the submitter (or if the submitter does not respond within the 10-day period), EPA will place that alternative generic name on the public TSCA Inventory. If the alternative generic name proposed by EPA is not acceptable to the submitter, the submitter must submit a revised generic name that meets the criteria in paragraph (f)(1) of this section and an explanation of how EPA's proposed generic name reveals confidential information. If EPA concludes that the submitter's revised generic name also does not meet the criteria in paragraph (f)(1) of this section, EPA will hold the notice of commencement for a period of up to 10 business days. Reporting requirements will not be considered to have been met and the substance will not be added to the TSCA Inventory during this period. If the submission remains deficient after this 10-day period, EPA will proceed with CBI review of the chemical identity claim and will likely deny the claim.

PART 723 – PREMANUFACTURE NOTICE EXEMPTIONS

23. The authority citation for part 723 continues to read as follows:

Authority: 15 U.S.C. 2604.

24. Amend § 723.50, by revising paragraph (l) to read as follows:

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

* * * * *

(l) *Confidentiality.* Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

* * * * *

25. In § 723.250, revise the introductory text of paragraphs (f) and (n) to read as follows:

§ 723.250 Polymers.

* * * * *

(f) *Exemption report for polymers manufactured under the terms of this section.* For substances exempt under paragraphs (e)(1), (e)(2), and (e)(3) of this section a report of manufacture or import must be submitted by January 31 of the year subsequent to initial manufacture. The report and accompanying claims must be submitted via CDX (<https://cdx.epa.gov/>), using the TSCA Section 5 Notices and Supports – ePMN application. See § 720.40(a)(2)(ii) for information on how to access e-PMN software. The notice must include:

* * * * *

(n) *Confidentiality.* Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

PART 725 – REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR MICROORGANISMS

26. The authority citation for part 725 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625.

27. Revise § 725.80 to read as follows:

§ 725.80 General provisions.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703, except as modified in this paragraph. In general, references to “chemical” or

“chemical identity” in part 703 are equivalent to “microorganism” or “microorganism identity” for the purposes of this part.

(a) In place of § 703.5(b)(3)(v), the following question applies: Has EPA, another Federal agency, or court made any confidentiality determination regarding information associated with this microorganism? If yes, please provide the circumstances associated with the prior determination, whether the information was found to be entitled to confidential treatment, the entity that made the decision, and the date of the determination.

(b) In place of § 703.5(b)(4), the following questions apply:

(1) Has the identity of the microorganism been kept confidential to the extent that competitors do not know it is being manufactured or imported into US commerce? If not, explain why the microorganism identity should still be afforded confidential status (*e.g.*, the microorganism is publicly known only as being distributed in commerce for research and development purposes, but no other information about the current commercial distribution of the microorganism in the United States is publicly available).

(2) Does the microorganism leave the site of production or testing in a form which is accessible to the public or to competitors? If yes, please explain what measures have been taken to guard against the discovery of its identity. Further, what is the cost to a competitor, in time and money, to develop appropriate use conditions? What factors facilitate or impede product analysis?

§ 725.85 [Removed]

28. Remove § 725.85.

§ 725.92 [Removed]

29. Remove § 725.92.

§ 725.94 [Removed]

30. Remove § 725.94.

31. Revise § 725.95 to read as follows:

§ 725.95 Public file.

All information submitted, including any health and safety study of a microorganism and other supporting documentation, will become part of the public file for that submission, unless such materials are claimed as confidential in accordance with this section. In addition, EPA may add materials to the public file, subject to subpart C of this part. Publicly available materials are available at the docket addresses in § 700.17(b)(1) and (2) of this chapter and on EPA's website.

32. Amend § 725.190 by revising paragraph (c) and adding paragraphs (e) and (f) to read as follows:

§ 725.190 Notice of Commencement of manufacture or import.

* * * * *

(c) *Information to be reported.* The NOC must contain the following information: Specific microorganism identity, MCAN number, and the date when manufacture or import commences. If the person claims any information on the form as confidential, the claim must be asserted and substantiated in accordance with the requirements described in part 703 and § 725.80, as indicated in EPA Form 7710-56. If the submitter wants the microorganism identity to be listed on the confidential portion of the TSCA Inventory, the microorganism identity must be claimed as confidential and also follow the certification, substantiation, and generic name requirements described in part 703 and paragraph (e) and (f) of this section.

* * * * *

(e) *Requirements for assertion.* Any person who asserts a confidentiality claim for microorganism identity must:

(i) Comply with the requirements of paragraph (f) of this section regarding submission of a generic name.

(ii) Agree that EPA may disclose to a person with a bona fide intent to manufacture or import the microorganism the fact that the particular microorganism is included on the confidential TSCA Inventory for purposes of notification under section 5(a)(1)(A) of the Act.

(iii) Have available and agree to furnish to EPA upon request the taxonomic designations and supplemental information required by § 725.12.

(iv) Make claims of confidentiality in accordance with the procedures described in 40 CFR Part 703.

(f) *Generic Name*. If a submitter asserts a claim of confidentiality for microorganism identity in a notice of commencement, they must provide a generic name.

(1) Generic names must:

(i) Be structurally descriptive (e.g., not a trade name); and

(ii) Be consistent with guidance on the determination of structurally descriptive generic names, developed in accordance with TSCA section 14(c)(4)(A) (e.g., *Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under TSCA*). Generic names for microorganisms may only mask the portion of microorganism identity that the submitter believes is proprietary (considering that the identity of a microorganism to be listed on the TSCA Inventory must include taxonomic designations (genus, species, and strain), key phenotypic traits, key genotypic traits and modifications, genetic material that has been introduced or modified, any vector constructs used, cellular location of introduced or modified genes, number and type of genes introduced or modified, and method of construction or modification). Taxonomic designation (in most cases down to strain) must be included in the generic name except where the submitter claims the taxonomic designation confidential, in which case the person making such claim must provide an explanation of why such masking is necessary to protect proprietary information. Additionally, the generic microorganism identity must include a statement regarding the function and stability of the genetic construct. This includes an indication of whether the introduced or modified genes are present on the chromosome or extrachromosomal.

(2) Generic names will be reviewed by EPA at the time of submission.

(i) If EPA concludes that a proposed generic name meets the criteria in paragraph (f)(1)

of this section, EPA will include that generic name in the public TSCA Inventory listing for that substance.

(ii) If the proposed generic name does not meet the criteria in paragraph (f)(1) of this section, EPA will notify the submitter concerning the deficiency via CDX, as described in § 703.5(h). EPA will provide ten business days to correct the deficiency and provide an alternative generic name that would be acceptable to EPA. If the alternative generic name proposed by EPA is acceptable to the submitter (or if the submitter does not respond within the ten-day period), EPA will place that alternative generic name on the public TSCA Inventory. If the alternative generic name proposed by EPA is not acceptable to the submitter, the submitter must submit a revised generic name that meets the criteria in paragraph (f)(1) of this section and an explanation of how EPA's proposed generic name reveals confidential information. If EPA concludes that the revised generic name also does not meet the criteria in paragraph (f)(1) of this section, EPA will hold the notice of commencement for a period of up to 10 business days. Reporting requirements will not be considered to have been met and the microorganism will not be added to the TSCA Inventory during this period. If the submission remains deficient after this 10-day period, EPA will proceed with CBI review of the microorganism identity claim and will likely deny the claim.

PART 790 -- PROCEDURES GOVERNING TESTING CONSENT AGREEMENTS AND TEST RULES

33. The authority citation for part 790 continues to read as follows:

Authority: 15 U.S.C. 2603.

32. Revise § 790.7 to read as follows:

§ 790.7 Confidentiality.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.